

# **“South Carolina Prepares for Pandemic Influenza: An Ethical Perspective”**

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# **“South Carolina Prepares for Pandemic Influenza: An Ethical Perspective”**

## **I. Executive Summary**

### **Pandemic Influenza in South Carolina**

An outbreak of a new influenza virus occurs about three times a century. Its rapid spread worldwide causes a pandemic. A pandemic is a global outbreak of a new disease. On June 11, 2009, the World Health Organization (WHO) declared that a pandemic of a new influenza A (H1N1) virus has begun.

Planning for an influenza pandemic requires South Carolina’s communities to be prepared to take care of themselves. Each community should be ready to identify and use local resources to last through many weeks of illness. It is estimated that up to 35% or nearly 1.3 million South Carolinians will become ill. All areas of the country will be affected at the same time. There will be few federal resources available.

### **The South Carolina Pandemic Influenza Ethics Task Force**

In October 2008, prior to the June 11 declaration of a pandemic of Influenza A (H1N1), planners at the S.C. Department of Health and Environmental Control (SCDHEC) met with doctors, university professors, members of professional organizations and ethics experts to form the South Carolina Pandemic Influenza Ethics Task Force. This task force has been working to identify and address the difficult decisions that could arise in a severe influenza pandemic. The Task Force is a subcommittee of the state Pandemic Influenza Coordinating Council. The group serves as an advisory body to SCDHEC.

The task force has sought and, at this state summit, is still seeking public opinion and input to battle shortages of resources and personnel that might arise in a pandemic. The task force developed recommendations to address difficult pandemic planning issues including:

- vaccines
- antiviral drugs
- hospital beds
- medical equipment such as ventilators
- healthcare provider manpower shortages
- the need to keep the public informed of the changing situation.

Most people have never faced a serious pandemic in their lives. There is a great amount of uncertainty surrounding the next influenza pandemic. That is why SCDHEC needs and values input from the public. The people of South Carolina can be better prepared and respond more

effectively if they understand the threats posed by a pandemic—and participate in designing strategies to address these threats.

### **Ethical Principles**

The task force identified four basic ethical principles that have been a guide for all of its work. They are individual liberty, community solidarity, trust and professionalism. Using these principles as a foundation, the task force has developed a set of policy recommendations to serve as guidance during a pandemic. The group measured the recommendations against ethical guidelines to ensure:

- 1) that the language used is clear to all who might be affected;
- 2) that the recommendations are reasonable and based on the best available scientific evidence;
- 3) that there is a procedure to monitor the recommendations; and
- 4) that the benefits and responsibilities of each policy recommendation are shared equally among any individual or group that might be affected by it.

The task force recognizes that the rights of individuals should be respected. Some rights might be restricted during a pandemic in order to protect the well being of the entire community. This is the charge of public health and that is why SCDHEC, the state's public health agency, is leading the effort to ethically plan for a pandemic influenza.

### **Workforce Recommendations:**

- Businesses should develop plans that will help them continue to function while up to 40% of their employees are absent. These plans should include directions for controlling the disease in their workplaces.
- Healthcare employers should plan to provide counseling for workers who suffer from stress and anxiety as a result of lengthy duty during a pandemic.
- Healthcare employers should purchase antiviral medications for their workers to use as prevention against the disease. These medicines can also be used to treat workers who become ill.
- SCDHEC and the S.C. Hospital Association should encourage the development of private antiviral stockpiles to protect all healthcare workers who will have direct contact with pandemic influenza patients.

- Healthcare employers should make sure that their workers have masks, gloves and other protective equipment and training to help them stay well during the pandemic.
- SCDHEC should work with healthcare employers to determine which job functions are most important for patient care. Those employers should train other workers to perform those functions to ensure their offices can continue to operate.
- Healthcare employers should talk with their employees about the need to continue to provide care for sick persons during the pandemic. These employees should know the penalties that could be enforced if they refuse to care for the sick.
- Healthcare employers should make plans to help each other during a pandemic.

#### **Disease Containment Recommendations:**

- SCDHEC should consider discouraging non-essential gatherings of people, in order to prevent the spread of the disease.
- SCDHEC should use voluntary isolation and quarantine procedures at the beginning of a pandemic outbreak to try to control the first outbreaks of the disease.
- SCDHEC should inform people of the benefits and drawbacks of isolation and quarantine, before isolation and quarantine are used.
- SCDHEC should provide clear written information to all health care facilities, public health officials and law enforcement about their roles and responsibilities in imposing isolation and quarantine.
- South Carolina should follow the Centers for Disease Control and Prevention priorities for the use of limited vaccine supplies.
- If the federal government allows it, then SCDHEC should consider reviewing and adjusting the priorities for the use of vaccine supplies based on scientific evidence.
- Guidelines should be developed to help the public decide whether they need hospital care or can be cared for at home.
- South Carolina should establish ways to provide care for large numbers of sick people in places other than traditional hospitals or clinics.

#### **Hospital Care Recommendations:**

- Healthcare entities should plan for a system to decide which patients should have the limited available medicines and treatment equipment.

- Hospitals should designate an employee(s) called triage officers to make the decisions about who will receive the limited medicines and equipment. This employee will be rotated and will not provide direct patient care while serving as the decision-making officer.
- Hospitals should plan in advance on how they will care for the large number of patients who become ill during a pandemic.
- If, because of a shortage of equipment, personnel or supplies, someone is not able or eligible to receive a certain treatment, then they or their family members should receive an explanation as to why they will not receive this treatment.

#### **Legal Recommendations:**

- Clinical practice guidelines and assessment tools for the triage and treatment of patients with pandemic influenza should be developed by the SC Pandemic Influenza Ethics Task Force.
- Clinical practice guidelines and assessment tools that address the allocation of scarce resources, including criteria for the withholding or withdrawing of ventilator support in health care facilities that are experiencing a surge in demand for services due to the influx of patients with pandemic influenza should be developed by the SC Pandemic Influenza Task Force.
- The South Carolina Pandemic Influenza Ethics Task Force should seek agreement, in the form of policies or letters of support, from medical professional groups and licensing boards on the use of clinical practice guidelines and assessment tools.

#### **Public Information Recommendations:**

- SCDHEC should provide adequate public information about influenza prevention and influenza care at home.
- Messages about how people can protect themselves from the influenza pandemic should be stated by public health and healthcare providers consistently throughout the pandemic.
- SCDHEC will not be able to control the information flow during a pandemic, but should guard against and address rumors and misinformation.
- SCDHEC must respond to the need for information by the public in a timely manner, using all communication tools available, such as the Health Alert Network, the 2-1-1 phone system and other available tools. All information should be shared with the public through the media.

## **II. Introduction**

### **A. Background**

On June 11, 2009, the World Health Organization (WHO) declared that a pandemic of a novel influenza A (H1N1) virus has begun. Historically, about every 30 years, or three times a century, an outbreak of influenza occurs with a new virus that results in rapid worldwide spread of the disease, causing a pandemic. Planning for a pandemic requires that South Carolina's communities prepare to be self sufficient, to identify and use local resources to last throughout many weeks of the spread of the disease. In a pandemic, all areas of the country will be affected at the same time. There may be few federal resources on which to count and it is estimated that up to 35%, or over 1,512,207 of South Carolina's citizens would become ill (based on the South Carolina 2006 population estimate of 4, 320,593).

Until recently, it was believed that the next pandemic would evolve from the highly pathogenic strain of avian influenza that appeared in humans in Hong Kong in 1997. At that time, South Carolina began developing a draft response plan for pandemic influenza. The state emergency operations plan for pandemic influenza was published in November 2004. In November 2005, the national pandemic influenza plan was released and preparedness efforts intensified across the country. In South Carolina, state and local planning summits have been held to draw attention to the critical and comprehensive preparedness plans needed for a pandemic. Regional and county pandemic influenza plans have been drafted and exercised.

By necessity, pandemic planning prepares for the worst and hopes for the "best", or the least pathogenic strain of novel virus. In Spring of 2009, years after pandemic planning had begun in South Carolina and months after the development of the Pandemic Influenza Ethics Task Force, the H1N1 influenza was reported in Mexico and soon after, appeared in the United States. South Carolina confirmed its first cases of H1N1 influenza in late April 2009. In June 2009, the World Health Organization officially declared a pandemic.

As of May 11, 2009, WHO estimates that the secondary attack rate of the novel virus ranges from 22% to 33% making it more contagious than seasonal influenza. In the last few years, pandemic planning has assumed that a severe influenza pandemic could strike between 15% and 35% of the population (See Appendix 3, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention "Pandemic Influenza Severity Index.") If 35% of South Carolina's population were made ill by the novel influenza, it is estimated that approximately 750,000 would seek outpatient medical assistance and up to 16,000 would need hospital care. Depending on the severity of the novel strain, there could be from about 1,300 deaths to over 25,000 deaths, if the disease severity increases. The seasonal flu kills an average of between 700 and 900 South Carolina citizens per year. The effects of a pandemic may last six weeks or more in a community. Although H1N1 currently has a low pandemic severity level

and a mortality rate that is similar to seasonal flu, health officials are watching its spread around the world and carefully monitoring the virus' effects for signs of mutations that could cause this virus to become more deadly to humans.

### **What would a severe pandemic mean to our state?**

During a severe pandemic, our already overburdened healthcare system would not be able to handle the enormous influx of people seeking medical care and needing hospitalization. Hospitals would not have enough beds, ventilators, or other medical supplies to care for the ill.

The federal government has estimated that 40% of staff within government entities and private sectors may be absent from work for about two weeks at various times during the height of a pandemic. Employees may be out of work because they are sick, caring for sick family members or for children who are out of school, or they may be under quarantine. Consider the implications of this rate of absenteeism on the ability of businesses and governmental entities, such as public works, fire, police, and emergency medical services to continue to provide essential services. Absenteeism may affect public utilities such as water and electricity, medical care and public health services, education, and care for special needs populations. Food supply (as well as other goods) may be affected due to the unavailability of truck drivers to drive for one to two weeks.

Prevention of the close gathering of large groups of people may be one way that the state may attempt to contain the disease. In a pandemic, it may become necessary for local governments to close schools to prevent the spread of the disease. Depending on the severity of the pandemic, school closures might last for several weeks. Because the H1N1 influenza in South Carolina did not appear to be highly virulent in the spring 2009 outbreak, only a small handful of schools with cases were closed. If, however, the virus becomes more severe and schools are closed more widely, then child care centers must also close in order to contain the disease. Employees will need to stay home to care for their children. Other steps to contain the spread of the disease might include canceling public events such as sporting events or concerts, closing public recreation facilities, and closing office buildings and shopping centers. Because of the highly contagious nature of a pandemic, religious institutions may need to provide means other than normal religious services and locations to provide spiritual guidance to their congregations. Large numbers of deaths may present special challenges to these institutions and to the state's coroners and funeral homes.

### **What preparations have been made in South Carolina for an influenza pandemic?**

As the public health agency for the state of South Carolina, SCDHEC prepares for a pandemic by planning for public health response and by working with and assisting other agencies and businesses in their planning efforts. A pandemic influenza annex was added to the State Emergency Operations Plan.



To oversee a coordinated response among government agencies, nonprofit organizations and the citizenry, South Carolina formed a Pandemic Influenza Coordinating Council that assessed current preparedness and developed strategies to deal with a pandemic influenza. To date, SCDHEC, with the acknowledgement and support of the Pandemic Influenza Coordinating Council has implemented the following strategies to mitigate the effects of a pandemic influenza:

- ▶ Conducted extensive state, regional and local planning, including a state-level pandemic influenza plan and eight regional-level plans, with support provided to local governments in the development of county plans
- ▶ Held Information sharing meetings to promote awareness and preparedness
- ▶ Developed a multi-media public awareness campaign, including brochures, videos aired on SCETV and public service announcements aired on commercial television stations
- ▶ Stockpiled antivirals, supplies and equipment for treatment of infected persons and for use by public health first responders
- ▶ Developed detailed planning for medical surge and mass fatalities, and
- ▶ Expanded disease surveillance and laboratory capabilities

#### **B. The Pandemic Influenza Ethics Task Force**

In October 2008, pandemic planners at SCDHEC, hospitals, universities and other ethics experts met and formed the South Carolina Pandemic Influenza Ethics Task Force. This Task Force has been working to identify and address the difficult decision-making issues that will arise in a severe pandemic. The Task Force is a subcommittee of the Pandemic Influenza Coordinating Council, and is an advisory body to SCDHEC. It was charged with the development of this document and the presentation and explanation of this document to the citizens of South Carolina.

The Task Force solicited public opinion and input for further development of decision-making policies related to the shortage of resources and personnel that will arise in a pandemic. This document addresses the following issues:

- What is the current situation regarding pandemic influenza preparedness and what are the present plans and future directions?
- What will the health care system look like during a severe pandemic, based on planning assumptions and models?
- What will be the health care system response, including home care recommendations, public information on when to seek physician's care, antiviral medicines, and hospital care?
- What are the decision points for deciding who needs and who receives specific treatments? Questions posed in the discussion include:

- Who decides?
- How do they decide?
- Who gets home care? Physician care? Pre-hospital triage? Care at alternate sites? At hospitals?
- Will the health care system look radically different?
- Who is cared for at home? Who do they call for help? Where do they go for care?

### **C. Task Force Process**

At the initial October 2008 meeting, a Steering Committee of the Pandemic Influenza Ethics Task Force met to determine the process and the issues that would be addressed in the document to be produced by the larger Ethics Task Force. Membership of the Steering Committee included representatives of South Carolina Department of Health and Environmental Control (SCDHEC), SCDHEC Region 6 Ethics Pandemic Influenza Panel, the South Carolina Board of Medical Examiners, the University of South Carolina School of Medicine, the South Carolina Hospital Association, the Medical University of South Carolina, the South Carolina Board of Nursing, The University of South Carolina Center for Public Health Preparedness, Anderson Medical Center, Coastal Carolina University, the South Carolina Nurses Association and legal representation.

The Steering Committee then invited additional representatives to begin the development of this paper. (See Appendix 2, "List of South Carolina Pandemic Influenza Ethics Task Force Members.") Invitations to participate in this Task Force were sent to:

- University of South Carolina School of Law
- SC Bar Association, Health Law Section
- South Carolina Association for Justice
- SC Board of Pharmacy
- South Carolina Home Care Association
- South Carolina Academy of Family Medicine Physicians
- South Carolina Christian Action Council
- Southern Baptist Convention
- SC Primary Health Care Association
- South Carolina Office of Rural Health
- South Carolina College of Emergency Physicians
- South Carolina Home Care Association
- Members of National Medical Associations
- American Lung Association in South Carolina
- South Carolina Society for Respiratory Care
- South Carolina Funeral Directors Association
- South Carolina Coroner's Association
- American Civil Liberties Union

- Media Associations
- Palmetto Project
- Harvest Hope Harvest Hope Food Bank
- Municipal Association of South Carolina
- South Carolina Association of Counties
- South Carolina Chamber of Commerce
- Contingency Planning Association of the Carolinas
- South Carolina Department of Education
- Members of the South Carolina Pandemic Influenza Coordinating Council

#### **D. Purpose and Goals**

Since November 2008, the Task Force has met monthly in work groups to discuss and develop statements of the pandemic issues and recommendations related to general ethical guidelines for decision making in public health and clinical practice.

The intent of this Task Force is to ensure that the South Carolina public has an opportunity to hear and understand the difficult decisions that may need to be made by both public health practitioners and health care providers in the private sector. The Task Force sought to provide this information and solicit comments and recommendations from the general public in a series of public hearings held throughout the state. The Task Force compiled the comments received from the public and addressed these comments in a revised version of the paper to effect recommended changes in state and local pandemic influenza plans. Final public comments based on the first draft of the paper will be sought and included at the State Summit to present the first draft of the paper that will occur in mid-July 2009.

### **III. Assumptions**

The assumptions cited in this document are the assumptions that have been used by medical personnel and planners since pandemic planning began in earnest several years ago.

There are several assumptions about the disease process that must be considered in planning a response. Because a pandemic will be a novel virus, that is, a virus that has adapted and is a new strain, susceptibility to the virus will be nearly universal. Based on the course of previous pandemics, the projected peak transmission period for the initial pandemic influenza outbreak will be six (6) to eight (8) weeks. At least two pandemic disease waves are likely. And following the pandemic, the new viral subtype is likely to continue circulating and to contribute to seasonal influenza. Information about the current H1N1 pandemic is still evolving. Pandemic plans must address all levels of pandemic severity in order for responses to be effective for all levels.

It is estimated that, on average, infected persons will transmit infection to approximately two other people.

The Department of Health and Human Services, Centers for Disease Control and Prevention (CDC) provides states with disease forecasting software to assist in developing planning assumptions. The 2006 South Carolina population estimates show a statewide population of 4,320,593. Of that, there are 1,165,847 school-aged children (0-19 years), 2,602,006 working adults (20-64 years) and 552,740 retirees (65+ years). Planning is conducted using attack rates of 15% (minimum), 25% (most likely), and 35% (maximum). Plans are made to prepare for the most widespread attack rate of 35%. Based on these planning assumptions for a severe disease strain, South Carolina could anticipate between 350,000 (15% attack rate) and 750,000 (35% attack rate) of outpatient visits to physician offices. South Carolina anticipates between 7,000 (15% attack rate) and 16,000 (35% attack rate) hospitalizations due to novel or pandemic-strain influenza. These figures are counted in addition to normal seasonal influenza outpatient visits and hospitalizations.

The demand for hospital resources will peak at week five (5) during an eight-week pandemic "wave." During this week, an expected surge due to the additional burden statewide caused by pandemic influenza-related cases would be an increase of an estimated 433 hospital admissions per day, an additional estimated 2,114 persons requiring hospitalization, an additional estimated 612 requiring the use of an ICU bed, and an additional estimated 306 requiring mechanical ventilation. There are currently a total of 1,284 ventilators in hospitals throughout the state.

Because of the shortage of hospital resources, health care may not be delivered in the usual manner. To meet this demand, existing health care standards will have to be altered to use resources in the most effective manner to save the most lives.

Pandemic planning estimates show that South Carolina may experience a range of deaths from 1,296 for the least severe pandemic to over 25,924 deaths in a pandemic with a severity level similar to the pandemic of 1918. These deaths are counted in addition to the deaths that will occur from seasonal influenza. Just as hospitals and healthcare workers will be overwhelmed by the number of persons seeking medical care, the death care industry, comprised of both public and private agencies, may not be able to process remains in the same amount of time in which funerals and burials normally occur.

Though a vaccine targeted specifically to the novel strain of virus would be the most effective pharmaceutical tool to combat the disease, the development of influenza vaccines is a time-consuming process. From the time a specific strain of influenza virus is identified, it takes about seven months until a vaccine to target this specific virus is ready for worldwide distribution. In past pandemic planning it was assumed that the demand for a vaccine targeted for the pandemic strain of virus will greatly exceed the supplies initially available. Therefore, we expect that rationing of available vaccine will be necessary. In periods of limited vaccine supply, public health clinics will be the predominant locations for influenza vaccine administration and a reduction or cessation of other public health programs may be necessary in order to provide supplemental personnel for specific immunization job actions. In the case of the release of the H1N1 vaccine, currently scheduled for Fall 2009, it appears that the

vaccine may be available in more abundant supply than originally considered in pandemic plans.

Limited antiviral medicines will be targeted for treatment of individuals with the infection.

Due to the anticipated delay in vaccine availability for possibly the initial four to six months of a pandemic and the limited availability of antiviral medications, non-medical interventions such as isolation and quarantine, closure of schools and discouragement of public gatherings will be necessary.

Absenteeism among the workforce is projected by the federal government to be approximately 40%. Workers in society's critical infrastructure, including healthcare workers (HCWs), may fear being exposed to the pandemic strain of virus and may choose to be absent from work. Staff levels may be significantly reduced due to high levels of illness and hospitalization and many may be lost due to significant mortality associated with the disease. The remaining workers may be psychologically affected by disease, family concerns, concerns about economic loss, or fear. Staff may also be reduced by the need for some workers to attend to family illness or to children remaining at home due to school closures. Health care facilities must plan for adequate infection control supplies to protect workers as they carry out their healthcare duties.

**Key Assumptions:**

- There will be little or no immunity to a pandemic influenza.
- One wave of a pandemic influenza outbreak will last six (6) to eight (8) weeks, with two or three expected waves of the disease.
- The demand for healthcare will exceed resources.
- Rationing of scarce medical resources will be necessary.
- The public will expect health care to be delivered in the usual manner.
- Absenteeism from work will be exacerbated by the need for the public to stay home to care for ill family members or from fear of contracting the disease.
- Once the specific strain of virus is identified, it will take approximately seven (7) months for a vaccine to be developed.
- Due to limited and delayed supplies of vaccines and antivirals, non-pharmaceutical interventions will be employed to reduce the risk of infections.

## **IV. Ethical Principles**

### **Introduction**

Recent large scale disasters, such as the destruction of the World Trade Center twin towers, Hurricane Katrina, the Asian tsunami, and the SARS epidemic, have received extensive attention in the media. They have reminded us of the fragile bonds that hold human communities together and of the interdependence of all peoples and nations.

Two factors play an important role in mitigating the harmful effects of large scale disasters among the people most directly impacted: the care with which responses are planned and the existence of a shared ethical foundation on which to base public policy. These factors largely determine whether efforts to deal with disasters are likely to succeed.

The outbreak of pandemic influenza poses a challenge to public health planners. A window of opportunity is open for publicly stating the required ethical foundations and to construct detailed plans for mitigating the harmful effects of pandemic influenza.

This document states the ethical foundations for plans made by the South Carolina Department of Health and Environmental Control and other partners in the event of pandemic influenza, and provides ethical guidelines for policy development. The precise extent and severity of such a pandemic cannot be known in advance, and may evolve with the disease, but clearly stated ethical bases on which to make policy and to act will serve our state well in the planning process. Well conceived plans will give public health officials and other professionals confidence that their actions will likely achieve the desired results and be supported by a public that shares their values.

### **Ethical Foundations**

Our society has a long-standing tradition of placing priority on certain values. Individuals have drawn upon our founding documents, their own religious traditions, and other sources for moral guidance. Despite the diverse sources, we agree that certain values are critical points of reference when we, as a people, face difficult circumstances such as an influenza pandemic.

#### **Individual Liberty**

Individuals should be given the maximum amount of liberty consistent with a like liberty for others. This should include self-determination in matters affecting their own welfare. It should also include freedom of movement and respect for personal privacy. Disasters produce circumstances in which certain liberties may be limited to protect the safety of others.

## Solidarity

Individuals live within communities and cannot flourish without the support of others. This mutual dependence means that the interests of the community must be considered in all decisions that affect the group. *Inclusiveness* ensures that all groups and interests are considered when decisions affecting the community must be made. *Respect for equality* means that every individual is of equal worth and deserving of consideration. Communities depend on *reciprocity*, and individuals should see working for the interests of others as contributing to their own well-being. Solidarity also requires the group to protect the most vulnerable members of the community.

## Trust

Trust in public servants and public institutions is essential to the maintenance of a strong sense of community. It is built by consistent observation of standards for public service. *Transparency* builds confidence by making clear to all what decisions are made and the bases on which they are founded. *Accountability* ensures that all who are charged with making decisions for the community will be held responsible for the consequences of their decisions. *Responsiveness* to all engenders trust, even if not all desires can be fulfilled. *Proportionality* is crucial for trust so that burdens will not fall unduly on particular individuals or groups.

## Professionalism

Communities elect, appoint, and provide licenses to certain individuals in the expectation that they will serve the interests of all in discharging their duties. Health care and public service are the professions most directly involved in public health emergencies, such as pandemic influenza. Among the standards that apply to professionals in such circumstances is an obligation to provide care, even in the face of personal risks. Care should be rendered without regard to ability to pay and without discrimination based on criteria, such as race, gender, religion, or sexual orientation. Communities must be able to trust professionals to steward resources in the most efficient manner to ensure maximal benefit for all. Furthermore, distribution of resources should be guided by the best scientific evidence available. Palliative care should be given to those for whom treatments are not available or are ineffective.

We endorse the following principles when making decisions:

- A principle of fairness suggests that all persons who are in a similar situation will have similar access to the medication that is available from public sector stockpiles. Availability of treatment will not be based on gender, race, ethnicity, citizenship, or ability to pay.

- A principle of autonomy allows organizations, businesses, and individuals to take steps toward pandemic influenza preparedness, including purchase and stockpiling of antiviral drugs. Promoting autonomy contributes to overall national preparedness, resiliency, and can increase the amount of antiviral drugs available potentially leading to community benefits. While autonomy may result in unequal access to antiviral prophylaxis, public sector stockpiles are targeted to provide a safety-net for all Americans to receive treatment in a fair and equal manner.
- Minimizing the harms of an influenza pandemic may require targeting resources to specific groups that protect health and safety and provide essential community services. We believe that targeting limited resources to protect societal interests is ethically appropriate.
- A principle of reciprocity means that workers who assume increased risks due to their occupation and who provide benefits broadly to society – such as healthcare workers, firefighters, and emergency medical services personnel – should be protected, if possible.
- Flexibility, defined as the ability to modify recommendations before the pandemic as more information becomes available and at the time of a pandemic when the characteristics of disease are known, also is important.

These principles are consistent with the values expressed in several public engagement and stakeholder meetings that were held. When asked to rate the importance of potential program goals, participants rated most highly the goals of protecting those who contribute to a pandemic response, who provide care for people with pandemic illness, who maintain essential community services, and who are at increased risk of infection because of their job.

## **Ethical Guidelines**

The foundations of ethics can seem straightforward and uncontroversial. At the same time, implementing ethics can be complicated and controversial, especially when guidelines are needed in emergencies or time sensitive tasks, such as responding to a pandemic. Guidelines can conflict, so that adhering to one leads to violation of another. Principles are often difficult to express in specific rules to guide real situations.

Nevertheless, guidelines can be useful in formulating and executing policy. No list can be satisfactory to all, but we recommend that the following guidelines be used to measure policies and actions against the ethical framework described above:

1. Policies for responding to pandemic influenza should be developed in advance of an outbreak.
2. Policy development should be open and transparent, and should include participation at some level by individuals and groups that will be subject to the policies.
3. Any proposed policy or action should:



- be stated in language that is clear to all whose interests are affected;
- be based on reasonableness and the best available scientific evidence;
- include procedures to ensure accountability;
- ensure that the benefits and burdens of any policy or action are shared equitably among affected individuals and groups

4. In developing a policy or proposing an action, individual liberties should be respected, but when others are likely to be adversely affected by an individual's actions or lack of action, the interests of the entire community should take priority over competing interests.

5. Advance planning should include a mechanism for continuously evaluating the effectiveness of policies and actions in the event of a pandemic, and a mechanism for reformulating policies based on these evaluations.

## **V. Pandemic Planning Goals**

There are three over-arching goals in the event of an influenza pandemic. All decisions are based on the goal of wanting as few South Carolinians as possible to get influenza, enabling as many South Carolinians as possible who do get influenza to survive the pandemic, and continuing essential life-maintaining functions of all sectors of South Carolina's infrastructure – public safety, healthcare, and commerce.

In pursuing these desired goals during a pandemic, every citizen should have the opportunity to be informed of the reasons for the actions taken by governments at all levels. Most importantly from an ethical point of view, we must strive to insure that every citizen recognizes that governmental actions that affect them are being administered with extreme attention to a fundamental and real sense of fairness. Unfortunately, there is the realization that, in situations of limited healthcare resources such as influenza vaccines, antiviral medications, and medical equipment, essential fairness will not always mean essential equality – this is the ethical burden of the need to ration scarce resources to achieve the overall public interest goals.

The discussion and recommendations below are based on the planning that was needed to prepare South Carolina for a severe pandemic. It is unknown which or how many of these recommendations may need to be incorporated for the response to the novel H1N1 pandemic, or future pandemics with unknown severity levels.

### **A. Workforce Continuity**

Maintaining continuity of the healthcare workforce needed to provide for the health and safety of communities during an influenza pandemic will be challenged by high rates of absenteeism due to illness, competing responsibilities for family needs, and concerns for personal safety. Of

particular importance will be the professional ethics and values that healthcare personnel apply to the decision to remain on duty in the face of these competing demands and concerns.

The South Carolina Pandemic Influenza Plan incorporates the generally accepted ethical constructs of duty to care and professional values while acknowledging the extreme working conditions and personal circumstances that must be reconciled at the personal and institutional levels in order to assure continuity of essential services during a pandemic event. The South Carolina Emergency Health Powers Act holds healthcare workers accountable for the duty to care principle without provision of exceptions for extenuating conditions by penalizing noncompliant workers with loss of professional license, certification, or vocational privilege.

The duty to care, in normal and disaster situations, is inherent in the professional codes of ethics of most health care professions. American Medical Association (AMA) principles of medical ethics state that, in providing patient care, except in emergencies, a physician may choose whom to serve. In emergencies such as pandemic influenza, physicians also have the responsibility “to participate in activities contributing to the improvement of the community and the betterment of public health”. The AMA Declaration of Professional Responsibility commits physicians to “apply our knowledge and skills when needed, though doing so may put us at risk.” This obligation is also reflected in the American Nursing Association Code of Ethics which stresses collaboration with other healthcare professionals and the public in promoting community efforts to meet health needs.

In choosing a profession, healthcare workers voluntarily accept the associated risks and enter into a social contract to be available during emergency situations. Historically many professional codes of ethics had explicitly addressed the obligation of duty to care during high-risk infectious disease epidemics. Perhaps due to the rarity of infectious disease epidemics in modern times, the specific language has disappeared from most professional codes though the inherent ethical principles remain.

The duty to care imposes a reciprocal duty for institutions and society to support and protect healthcare workers from the health, safety, and economic risks associated with continuing to provide essential services in an infectious disease epidemic. In order to maximize the continuity of the healthcare workforce in an infectious disease epidemic, continuity of operations plans must balance ethical and social obligations with the competing and legitimate concerns of healthcare workers for the safety and security of themselves and their families.

To help health care workers (HCWs) meet these duties, healthcare institutions have an equal obligation to provide appropriate emergency and infection control training. Front-line clinicians should be provided personal protective equipment, post-exposure antiviral prophylaxis when indicated, and priority to receive vaccination. Health care workers should also be provided supportive services such as counseling when necessary, liberal family and sick leave, and other family support such as child care. Surveys of clinicians find that availability of institutional resources and worker protection facilitates workplace continuity.

Clinicians and facilities should negotiate and plan how best to cover the expected surge in demand for clinical services before events occur and determine if workplace sanctions for noncompliance with expected responsibilities should be implemented. Examples may include deferral of routine visits or elective surgical procedures, providing telephone services in lieu of office visits, and prescribing more than one-month's supply of routine medications.

Developing and implementing a continuity of operations plan (COOP) in all healthcare settings regardless of size or scope is the essential first step in assuring that expectations for workforce continuity are supported by mutually reciprocal principles of ethics and fairness. COOPs should clearly define expectations for workers by identifying essential job functions and services that must be maintained in a pandemic. The development of procedures and assurance of resources needed to provide maximum protection for workers and their families are also fundamental to operational continuity planning.

SCDHEC will assist healthcare organizations with the process needed to identify and designate clinical and non-clinical healthcare workers deemed to be critically necessary during pandemic, clarify use of quarantine or isolation, and help define responsibilities of vital but non-clinical employees. The Emergency System for Advance Registration of Volunteer Health Professionals (ESAR-VHP) and the Medical Reserve Corps (MRC) may provide supplemental volunteer personnel to support clinical and public health practices when available. SCDHEC will assist healthcare organizations and facilities in developing fair and responsive policies.

## **B. Disease Containment Measures**

The approach of Public Health to a crisis is to look at the public as a whole, not focusing upon the individual other than his role as a member of the public who may benefit from or be harmed by a public health action. It is the role of Public Health to be concerned with the prevention, spread and mitigation of illness, in as fair a way as possible, for the community as a whole.

The use of non-pharmaceutical community containment interventions by public health will be necessary to control the spread of pandemic influenza. Among them are the use of social distancing and isolation and quarantine measures to prevent disease transmission. Social distancing discourages or presents large, non-essential social gatherings when necessary to prevent exposures of large numbers of people. It may not be feasible to suspend all large gatherings. Appropriate recommendations will be given for disease containment measures for events like mass immunization clinics, blood drives, funeral services, etc. Isolation quarantine measures use isolation to seclude an individual with a contagious disease, and quarantine to seclude an individual who has or who may have been exposed to a contagious disease and who may later develop the disease and become contagious. Isolation and quarantine measures will enhance other disease control strategies. Isolation and quarantine measures have been used traditionally to prevent the transmission of communicable diseases and the evidence that these interventions are likely to be effective in limiting disease transmission are drawn from the

effectiveness of the measures in controlling the spread of disease in previous pandemics, during the Severe Acute Respiratory Syndrome (SARS) outbreak and with other communicable diseases in hospital settings.

Pandemic Influenza assumptions related to isolation and quarantine measures affecting the public health are: 1) non-medical interventions will be necessary due to the anticipated delay in vaccine availability for possibly the initial four to six months of a pandemic. Additionally, limited antiviral supplies will be targeted for individuals who are either at highest risk of exposure to disease, or who are at high risk of complications from infection; 2) public health has authority under the Emergency Health Powers Act to use isolation and quarantine as a disease control measure; 3) isolation measures may involve both health care facilities and home settings; quarantine measures will be largely in-home settings but may also involve work or other settings and will rely heavily on voluntary cooperation due to limited resources for enforcement.

The primary goal for implementing isolation and quarantine is to minimize transmission. Isolation and quarantine measures are intended to delay the peak of the epidemic therefore allowing the development and implementation of other countermeasures. Limiting disease transmission will also decrease overall illness and death rates and thereby the overall impact of the epidemic on the population.

Isolation and quarantine measures will be used primarily during early pandemic influenza transmission in South Carolina. The trigger will be the identification of the first cases of the pandemic flu strain in South Carolina or the surrounding geographic area. Isolation and quarantine measures will be less effective once disease becomes widespread because maintaining the intervention will quickly exhaust limited public health resources.

South Carolina relies on voluntary cooperation with isolation and quarantine measures. Most individuals are willing to comply with voluntary measures and understand the value for limiting the spread of the disease. Mandatory orders are issued only in the rare cases where individuals do not comply and pose a significant health threat to others.

By definition, public health is the obligation to assure the health of the "whole." Individual rights may be limited if they risk endangerment of the public health. The ethical value of individual rights is balanced by the obligation to protect public health by limiting the spread of disease. Although individuals who are ill or possibly incubating disease will be disadvantaged if they are placed under isolation or quarantine, these interventions are fairly applied to the population because the intervention is based on disease state alone and not any other societal considerations. Some individuals, however, will be more disadvantaged by these restrictions. For example, those who do not have paid leave, or those that serve as the primary provider for a household will suffer a greater economic burden from isolation and quarantine measures. The decision to impose these restrictions on individuals in order to prevent individuals from transmitting disease, thus hampering initial public health efforts to slow the spread of

pandemic influenza, must be balanced against individual rights and the potential disruption disease containment measures may cause.

How can burdens of this approach be minimized? Disagreement with or potential rejection of isolation and quarantine measures can be diminished by advance communication of goals and potential benefits and drawbacks to the general public. The communication plan should be developed to reach disadvantaged and non-English speaking populations. Public Health is primarily responsible for framing and disseminating information about the potential for isolation and quarantine measures to slow the spread of disease and the mechanism by which isolation and quarantine will be implemented through public health orders. Personal liberties will be affected with the implementation of isolation and quarantine and other disease containment measures. Mechanisms do exist for judicial review for mandatory public health orders for isolation and quarantine, and these types of public health orders are subject to judicial review in the South Carolina court system. SCDHEC assumes the responsibility of assuring that the basic needs of individuals placed under mandatory isolation or quarantine orders are met.

Disseminating guidance to all entities where individuals may be isolated is also needed to address the joint role that health care facilities, public health and law enforcement may have in imposing isolation and quarantine. The possibility of the need to quarantine individuals in certain high-risk occupations should also be communicated in advance.

### **C. Allocation of Vaccines and Antiviral Medications and Other Countermeasures**

In pursuing the three previously mentioned over-arching goals during a pandemic, it is important that every citizen has the opportunity to be informed of the reasons for the actions taken by governments at all levels. Most importantly from an ethical point of view, government and health care providers must strive to ensure that every citizen recognizes that actions that affect them are being administered with extreme attention to a fundamental and real sense of fairness. Unfortunately, in situations of limited healthcare resources such as influenza vaccine and antiviral medication, essential fairness will not always mean essential equality – this is the ethical burden of the need to ration scarce resources to achieve the overall public interest goals.

#### **1. Vaccines**

Within the context of the goals and ethical principles outlined above, the South Carolina Pandemic Influenza Task Force supports five important objectives:

- \* protecting those who are essential to the pandemic response;
- \* providing care for persons who are ill;
- \* protecting those who maintain essential community services;
- \* protecting children and other vulnerable populations; and

\* protecting workers who are at greater risk of infection due to their job.

Given the high likelihood that vaccine supplies will be limited at best in influenza pandemic, priorities must be set for the distribution of vaccine. At the time of the development of this document, the US Centers for Disease Control and Prevention (CDC) has recommended such priorities (See Appendix 4, "Table 1. Vaccination target groups, estimated populations, and tiers for severe, moderate, and less severe pandemics as defined by the Pandemic Severity Index PSI") and we endorse them for South Carolina. The Table describes the members (tiers) of each component of the population and briefly describes the rationale for the priority assigned. A system of tiers is a necessary method for determining distribution of scarce resources, even though the tiers may change.

Among groups targeted for vaccination are workers with critical skills, experience, or licensure status whose absence would create bottlenecks or collapse of critical functions, and to protect workers who are at especially high occupational risk. In general, all groups designated for vaccination within a tier have equal priority for vaccination. Vaccine allocation within a tier will be proportional to the populations of the groups in the tier, though changes in this allocation scheme at the time of the pandemic may occur based on vaccine supply, the impacts of the pandemic, and the specific needs identified at that time. It is expected that further national guidance will become available to more specifically define critical occupations and population groups whose members should receive early vaccination and to provide guidelines to employers on the proportion of their workforce that may be prioritized for vaccination.

While vaccination priorities reflect the primary ethical value of essential fairness, it should be noted that the tiers are not "equal" since the scarcity of vaccine, especially in the early waves of the influenza pandemic, would mean that those in lower tiers may not receive vaccine and will go unprotected until those in higher tiers have been vaccinated.

During the period of imminent threat of a pandemic and especially during the first pandemic wave, SCDHEC will need to continuously examine and adjust vaccine priority tiers and sub-tiers to reflect the severity of the pandemic and to maximize survivability and minimize infection rates among all groups in South Carolina. The Task Force specifically recommends that there be flexibility in adjusting vaccination priorities if allowed by the federal government. To maintain every citizen's sense of essential fairness, the reasons for any adjustment of the established vaccination priorities should be fully communicated to the general public.

## **2. Antiviral Medications**

Antiviral medications can be used to treat the sick or to prophylax, or prevent illness in, people who have been exposed but are not yet sick.

For H1N1 influenza, early treatment (within the first two to three days of the appearance of symptoms) with an antiviral medication is effective in decreasing the symptoms of the disease and decreasing the risk of pneumonia. Early treatment has been shown to decrease hospitalization by about half, and will also decrease mortality. Treating earlier after the onset

of disease is most effective in decreasing the risk of complications and shortening illness duration. The use of antivirals as post-exposure prophylaxis to prevent infection is a means to effect disease containment and to protect healthcare workers and others. A pre-exposure prophylaxis strategy would require continuous administration of antiviral medication throughout the first pandemic wave. This strategy increases the risk of side effects or the occurrence of drug resistance and could more quickly exhaust limited resources. For these reasons, pre-exposure prophylaxis is not generally recommended.

Persons who will have close and recurrent exposure to pandemic illness (e.g., healthcare workers or emergency responders who have very high or high exposure occupations) should use personal protective equipment. Appropriate personal protective equipment may be particularly useful for increasing worker confidence and may discourage unnecessary absenteeism due to fear of becoming ill. In healthcare and emergency service sectors, workers who provide direct patient care or have high-risk exposure must be identified, and plans must be made for providing personal protective equipment and rapidly identifying unprotected exposures in order to initiate post exposure prophylaxis rapidly to prevent illness.

The primary public source of antiviral drugs for a pandemic treatment response will be the public supply of antiviral drugs that have been stockpiled through the South Carolina federal allotment. These stockpiles can be used only for treatment. The ethical principle underlying the treatment strategy assumes that public sector stockpiles should be prioritized for treatment because it represents the most efficient use of a limited drug supply, because prophylaxis for some while others are denied treatment would not be perceived as equitable, and because other mitigation measures can be implemented to protect workers and reduce the risk of exposure and infection. The CDC has determined that post-exposure prophylaxis, while reasonable and desirable, will have to be funded by private sector employers, including health care institutions. Given the high likelihood that antiviral drug supplies will be limited at best in an influenza pandemic, priorities must be set for the distribution of such drugs. A principle of fairness suggests that all persons who are in a similar situation will have similar access to the medication that is available from public sector stockpiles. Availability of treatment will not be based on gender, race, ethnicity, citizenship, or ability to pay. (See also Appendix 5, U.S. Department of Health and Human Services, "Guidance on Antiviral Drug Use during an Influenza Pandemic", Table: Settings and strategies for antiviral drug use during an influenza pandemic.)

The ethical principle of autonomy calls for organizations and businesses to take steps toward pandemic influenza preparedness, including purchase and stockpiling of antiviral drugs where appropriate. Promoting autonomy contributes to overall national preparedness, resiliency, and can increase the amount of antiviral drugs available potentially leading to community benefits. While autonomy may result in unequal access to public sector stockpiles are targeted to provide a safety-net for all Americans to receive treatment. Unlike vaccines, where each tier would be protected in turn as more vaccine is produced, for antiviral medications, the number of priority groups that can be covered theoretically would be known at the start of the

pandemic based on the amount of drug that is stockpiled. Additional supply that would become available during the pandemic could provide some flexibility.

Although, ultimately, it is the responsibility of health care worker employers to stockpile antivirals for employee and personal protective equipment, the Task Force further recommends that the SCDHEC and the SC Hospital Association establish a joint working group to identify and encourage the development of antiviral stockpiles and funding necessary to implement this recommendation.

In lieu of funding availability, healthcare facilities should support solidarity by adopting mutual assistance agreements among themselves and community providers to share institutional resources.

This recommendation is consistent with our main goals of pandemic influenza response: minimizing influenza rates, while at the same time contributing to the essential healthcare component of South Carolina's critical infrastructure. While this recommendation could conceivably lead to other South Carolina citizens not receiving antiviral medications that are in short supply, the maximum availability of health care workers during a pandemic will contribute in the fairest manner to the interests of all citizens who seek health care during that critical period.

#### **D. Triage**

An important consideration in the ethical decision making process is the determination of which influenza patients will receive care with the limited hospital resources. Triage, or the “sorting” of patients based on severity of illness combined with likelihood of survival, will be done on two levels: pre-hospital, or prior to hospital admission, and in-hospital triage.

Pre-hospital triage includes the process of identifying resources for care for individuals who do not need hospital care, identification of other resources to care for individuals when hospital resources are exhausted, and provision of health education to the public to assist them in making decisions about their own care.

Pre-hospital triage also provides guidelines for out-patient and emergency healthcare workers on treatment, resources, stewardship and handling difficult ethical issues when they arise. Current public expectations about access to care and the levels of health care that may be provided in a pandemic must change to reflect the realities of a public health crisis.

The implementation of pre-hospital triage in a pandemic significantly differs from traditional, daily, hospital triage in that, the triage, or sorting, is being done by the individuals themselves, who have no professional ethical obligations related to their own care.



## **1. Need for Pre-Hospital Triage**

Pre-pandemic planning indicates that the number of hospital beds available to manage the consequences of an influenza pandemic will be inadequate. Given the scarcity of hospital-based resources, clarity regarding the goals of pre-hospital triage is essential in the preservation of public trust, and possibly even public order.

Triage begins with an explanation of options to those in the public and the healthcare fields who are doing the sorting. Pre-hospital triage activities should provide accurate and timely information to the public regarding disease prevention measures necessary to reduce disease transmission. They should include home care information and resources for community-based provision of care. Planning for pre-hospital triage should strive to assure that allocations of treatment resources are made with the goal of reducing illness, hospitalization and death. Additionally, healthcare planners must develop and implement standardized pre-hospital triage procedures to assure that those seeking treatment are sent to an appropriate care location.

Since the first “sorting” is done by the ill or those caring for them in the community, it is critical that the public receives sufficient information to perform self-triage activities. Options for care that may be considered by the public or chosen by healthcare providers may include:

- Self-care,
- No care,
- Outpatient/primary care,
- Care in the Emergency Room,
- In-patient care,
- Care in an off-site non-traditional facility, or
- Palliative (hospice-type) care.

Assignment to any of these venues or systems will imply varying outcomes to those being sorted, and may be seen as having varying values. An equitable system assures that the capacities and levels of care available from these systems are clearly explained and understood by all those who may be sorting themselves or others to these options.

## **2. Planning for Pre-Hospital Triage**

Pre-hospital triage procedures, in order to be accepted and successful, must be developed and adopted well in advance of a pandemic. The first task is to develop and disseminate public information in a timely manner. Pandemic planners assume stewardship of knowledge resources as they identify appropriate public information materials (disease prevention messages, home care information, etc) and methods to disseminate information to the public.

A second critical step in planning for pre-hospital triage is to identify systems of care. This includes identification of appropriate traditional and non-traditional healthcare facilities

(alternate care sites, community care centers/shelters) to treat those with influenza, as well as defining and assigning roles to relevant partners for the operation of the above facilities.

Development of pre-hospital triage systems well in advance increases the likelihood of adherence to the ethical frameworks outlined by this taskforce. Public engagement and involvement in advance are essential to building public good will and trust, as planners support the principle of collaboration. Consistency in application of “sorting” standards, and basing the triage procedures on sound scientific evidence supports the principles of equity/fairness and reciprocity. Non-traditional healthcare facilities with defined goals, admission criteria, management standards and regulatory criteria support the principles of collaboration and stewardship.

### **3. Potential Burdens of Triage**

While equality and fairness are core ethical values, it is recognized that these may not be present in a public health crisis. It can be assumed that not all persons will have access to appropriate education or public information materials and needed resources. This handicaps the ability of these persons to “sort” themselves or their loved ones appropriately into the best model of care.

The principle of fairness in pre-hospital and hospital triage demands that individuals receive explanations about why they or their family members are not eligible for certain treatments. It is understood that receiving an explanation does not always lead to acceptance, but it does assure that the same standards are applied to all those seeking care, when the explanations are standardized.

The potential burdens of triage can be minimized if the public is engaged in development of public educational materials prior to a pandemic. This collaboration may enhance the stewardship of resources in a time of crisis. Planners must assure involvement of “hard to reach” populations in development of materials/resources and the methods to distribute information concerning influenza prevention, treatment and pre-hospital triage.

Those making “sorting” decisions in a time of crisis must be provided with accurate information in an efficient and timely manner (real time) during Pre-Pandemic, Pandemic and Post-Pandemic times. To this end, development of a pre-hospital triage tool is needed; it must be based first on those clinical and epidemiological factors related to controlling the spread of, and lessening the impact of, the disease on the unaffected population.

Public Health would be expected to take the lead in guiding the establishment and management of non-traditional healthcare facilities in which individuals may be sorted prior to any hospital treatment. The goals of these facilities include (1) provision of care for persons who cannot provide care for themselves, and (2) provision of care to those whose illness

exceeds the capacity of their caregivers in the home. It is expected that Public Health and key Health Care Partners will set aside self-interest and territoriality to promote collaboration to achieve these goals.

Finally, it is recognized that inequitable distribution of resources may be a part of assuring that the healthcare system is best prepared to respond to a prolonged event. For example, workers providing certain key services, such as laboratory workers, vaccine or antiviral producers, healthcare providers and law enforcement personnel who have critical roles to play in the control and impact of this disease may be “sorted” to higher priority groups for treatment, or prophylaxis, etc. The “good” of public order may be valued more than the “good” of free will in a time of crisis.

#### **4. Primary Care’s Role in Pandemic Triage**

Primary care provider settings include physician’s office, community health centers, outpatient clinics, urgent care centers and other community health care providers. If a member of the public, self-triages to a physician’s office, community health center or clinic, then the primary care provider must determine the triage status of that person.

A major primary care responsibility is assessment and referral of influenza-like illness by category. An adult self-assessment tool (Appendix 6, Clinical Practices: Adult Self-Assessment Tool) may be used to facilitate this process. If the tool identifies no influenza-like illness, the patient needs no treatment, but receives educational material on influenza. If the patient needs additional assessment for diagnosis, clinicians should consider starting treatment and referral for further diagnosis (x-ray or lab testing). If the patient has identifiable influenza-like illness, clinicians start treatment and assess for discharge home (alone or with community supports) or referral to surge center; sufficiently ill or vulnerable patients require follow-up in 24 to 48 hours to assess status. If the patient has identifiable influenza-like illness with high risk criteria, clinicians should arrange transfer to hospital for additional assessment or admission.

The pediatric patient population may require additional assessment based upon physical examination, co-morbid conditions, individual risk factors, and the effect of the pandemic virus in this population.

#### **5. The Demand for Acute Care, the Role of Triage and the Allocation of Critical Resources in the Hospital Setting**

Most patients presenting to the hospital emergency departments may encounter a triage screening process utilizing the primary screening tool. Based upon that assessment, patients may be triaged home, into an alternate care site, or into the emergency department for further assessment or hospital admission.

Based upon FluAid/FluSurge, the forecasting models developed by the CDC, pandemic influenza infection (attack) rates may approach 35% of the general population. The FluSurge forecast assumes each hospitalized influenza patient requires an average of either 5 (non-Intensive Care Unit) or 10 (Intensive Care Unit) days of hospital care with 100% using an acute bed for 5 days, 15% using ICU beds for 10 days, and 7.5% using ventilator support for 10 days. Many hospitals currently operate at full capacity with very little capability to expand their abilities to care for a surge in patients (surge capacity). Pandemic influenza easily will overwhelm hospital resources.

<b>Impact of Pandemic with 25% Attack Rate on Hospital Resources: Additional Resources Required in Week 5</b>						
<b>Location</b>	<b>Population</b>	<b>Total Licensed Hospital Beds</b>	<b>Licensed ICU Beds</b>	<b>Additional Hospital Admissions Per Day in Week 5 Only</b>	<b>Additional Admissions Needing ICU Beds Per Day in Week 5 Only</b>	<b>Additional Mechanical Ventilator Needs Per Day in Week 5 Only</b>
Statewide	4,320,593	11,764	1,176	433	612	306
Region 1	467,598	1,141	70	49	69	34
Region 2	884,891	2,682	273	88	125	63
Region 3	845,496	2,437	276	91	129	65
Region 4	552,667	1,799	187	55	78	39
Region 5	307,362	653	57	31	44	22
Region 6	334,792	751	71	36	51	26
Region 7	603,178	1,771	203	58	82	41
Region 8	224,589	530	39	24	34	17

The South Carolina populations that are at high risk for seasonal influenza include:

- 1) people of all ages with heart conditions and chronic lung conditions, such as cystic fibrosis, asthma or emphysema;
- 2) residents of long-term care or other chronic care facilities, due to their environmental exposure regardless of their age or chronic conditions;
- 3) people with compromised immune systems, such as diabetes, other metabolic diseases, cancer, renal disease, anemia, HIV, or sickle cell anemia;
- 4) children on aspirin for conditions like juvenile rheumatoid arthritis because of Reye's syndrome risk;
- 5) children less than two years old , all of whom have a general lack of immunity;

- 6) pregnant women in the second and third trimester due to their increased risk of cardio-respiratory diseases and stillbirths;
- 7) healthy people aged sixty-five years and older because of moderately increased risk of respiratory complications.

During pandemic influenza, an unknown proportion of other people within South Carolina will develop health complications. This will depend upon pandemic strain characteristics and susceptibility of the population. Although the current H1N1 pandemic is a lower severity, planning must address a high severity pandemic. This planning assumes that, with the FluSurge estimate for a 35% attack rate, admitted patients will immediately affect ICUs and rapidly increase pressure on the acute bed supply. By the end of week one influenza patients may require 37% of ICU bed and 16% of acute care bed capacity. To meet pandemic demands, hospitals must develop phased surge capacity. (See Appendix 7 Hospital Capacity.) Gaining surge capacity will require deferral of the care of non-influenza patients and dynamic use of influenza triage, with admission/discharge criteria constantly adjusted to hospital capacity.

These approaches to optimum hospital utilization affect physical capacity, hospital staffing, and clinical practices phased to pandemic stages. Despite these efforts the most critical shortages will be shortages of respiratory support, including ventilators and critical care beds.

Triage reflects responsible allocation of resources and occurs daily in the health care environment. Routine triage focuses on how best to serve individual patients. Clinicians direct all available needed resources to care for each patient, giving priority to the most severely ill and treating everyone equally as possible within categories of severity.

Disaster triage shifts focus from preserving one life toward preserving as many lives possible with available resources. This occurs because using limited curative resources on one person with expected high probability of dying may cost the lives of several others. Similar triage happens in community settings experiencing small scale disasters whenever immediate needs overwhelm available resources. When pandemic influenza exhausts hospital surge capacity and usual health system resources in South Carolina, the Governor may invoke the Emergency Health Powers Act and signal clinicians to start community-focused triage state-wide. (The declaration of the Emergency Health Powers Act may occur in a severe pandemic, or may not be declared, depending on many factors, including pandemic severity level and demand for resources.)

Disaster or community-focused triage ensures fair and equitable allocation of scarce resources and maximizes benefit to the population at large. This approach reflects federal and state goals for pandemic influenza to minimize serious illness and overall deaths. During community focused triage, designated triage officers will use pre-determined clinical decision rules to make allocation decisions, with separate medical personnel rendering treatment. Hospitals will designate personnel to serve in the role of triage officer. Triage officers will not provide direct patient care while serving in this role, but will rotate into treatment roles to limit bias in triage

decisions. Adoption of the clinical decision rules for use in community-focused triage requires transparency and public endorsement. (See Appendix 8, “Specific Clinical Practice Guidelines.”)

Community- focused triage for critical care does not challenge or contravene ethical doctrine but is a practical application of ethics. Use of a clinical decision tool ensures fairness and justice. Under circumstances which may expose vulnerable people to inequitable treatment, clearly defined and transparent criteria protect such individuals from inequities. Community-focused critical care triage does not deny care, because all patients receive care. Every human life has value, and every human being deserves respect, caring and compassion. Patients triaged from critical care will receive out-patient treatment, non-critical acute care, or palliative care.

In the United States an overwhelming crisis, such as pandemic influenza, justifies community-focused triage ethically, legally and morally, when all resources approach or risk exhaustion. This protocol is not a first step toward resource rationing under ordinary circumstances.

Triage officers require training for outpatient and hospital settings. Standardized outpatient evaluation will identify patients who need hospitalization and who should receive treatment at home or in outpatient facilities (see Prehospital Triage). Admission orders, following initial surge center or emergency department evaluations, may include non-invasive ventilatory support; however, triage officers will determine who may received critical care, specifically ventilator support, based upon Sequential Organ Failure Assessment (SOFA) as a decision rule. See a more detailed description of SOFA in Appendix 9.

The SOFA score triage tool uses general physiologic parameters. SOFA applies to a wide range of critical patient conditions and is not a disease-specific scoring system. Although not ordinarily used to ration critical care resources, under pandemic conditions SOFA design permits such allocation, particularly use of ventilators. Critical ventilator decisions will include both withholding access and withdrawing ventilator support. Greater pandemic severity will require more frequent SOFA scoring. As the pandemic evolves, local hospitals’ ethics committees and consultants periodically should review triage criteria and clinical decisions to ensure fairness.

In the rare case that a triage officer and/or the attending intensivist may believe an initial assessment of mortality risk does not match a particular patient, a committee or process should be established to review the case.

SOFA-based triage offers prognosis for short-term survival to “save the most lives.” However, during severe pandemics ventilator allocation may require choosing between patients with equal SOFA scores. In these cases other ethical criteria may apply, for example, maximizing the number of “life-years” saved and prioritizing younger patients to offer opportunities to live through life’s stages. Appendix 10 “Multi-principle strategy for ventilator allocation” illustrates this multi-principle strategy for ventilator allocation.

Severely ill people, ineligible for critical care including ventilator support will be triaged into palliation. They will receive care to relieve the suffering caused by life-limiting illnesses and to

maximize quality of remaining life. Severe pandemic influenza will impose pressures of overcrowding, limited resources, and large numbers of dying adults and children; the need for palliative care will expand. However, palliative care deliberately neither hastens nor postpones death. By providing relief from pain and other distressing symptoms, palliative care affirms life and regards dying as a normal process. When deaths occur, palliative care helps as possible with family bereavement.

#### **F. Public Risk Communication Recommendations**

A pandemic virus is, by its nature, a new virus. Because of this, there will be very little known about its severity and ability to cause illness during the early stages of a pandemic. In order to remain as transparent as possible SCDHEC and its partners must educate the public on this lack of information, why so little is known about the virus, what is being done to learn more, and what people can do to protect themselves. These protective messages must be consistently stated throughout the pandemic.

The public's response to the threat posed by the 2009 outbreak of H1N1 in South Carolina was very helpful in preventing the rapid spread of the illness. Those who were asked to either voluntarily quarantine or isolate themselves did so without resistance, thereby assisting public health's efforts to slow the spread. Similarly, the media frequently stressed the simple protective steps that anyone could employ --- covering your cough, washing your hands, staying home when sick, staying away from others who appear to be sick, and living a healthy lifestyle through diet, rest and exercise. Without a doubt, this cooperative spirit among the media and public helped prevent a potential growth in the number of cases.

Public health will not control the information flow during a pandemic. Technology will enable a much faster flow than during any previous pandemic period. Very little information will be available early in the outbreak. It becomes necessary to attempt to guard against the spread of rumor and disinformation. With many viruses typically named for the animal of origin (e.g. "swine flu" and "bird flu"), information must reflect the safety of the nation's food chain through the use of biosecurity measures on U.S. farms. Without such information, those industries could be falsely stigmatized or economically damaged by the public's refusal to eat their products.

The public will rely heavily on their healthcare provider to sort thru the array of facts and myths to provide the most accurate information possible. Public health must respond with accurate information in a timely manner by way of the state's Health Alert Network and other available channels. Subsequently, that information should be shared with the public through the media in the continued effort to remain transparent.

## G. Legal Recommendations

The Legal Work Group's contribution addresses the potential tort liability of Licensed Health Care Providers (LHCP) during a Pandemic Influenza Public Health Emergency (PIPHE). This section begins with a brief discussion of tort liability and discusses how clinical practice guidelines could factor into a medical malpractice lawsuit following a PIPHE in South Carolina.

Tort liability is a serious issue affecting our modern health care delivery system and arises in several contexts, such as when a patient suffers harm or dies during a medical procedure. Medical malpractice claims are generally based on negligence theories. In order to successfully sue a LHCP, the injured party must prove the following elements by the greater weight of the evidence: (1) the LHCP owed a duty of care to the injured party; (2) the LHCP breached the duty of care; (3) the breach of the duty caused the injury; and (4) the injured party suffered damages. Ultimately, these issues are "questions of fact" to be decided by a judge or jury when a party claims to have been injured by a LHCP.

In medical malpractice cases, the duty of care is the degree of care observed by a competent practitioner acting in the same or similar circumstances. King v. Williams, 276 S.C. 478, 482, 279 S.E.2d 618, 620 (1981). A breach of that duty is the "the failure to do what an ordinarily careful doctor in the defendant's field of medicine would have done under the same or similar circumstances or the doing of something that an ordinarily careful doctor would not have done under the same or similar circumstances." "Medical Malpractice: Breach of the Standard of Care," Judge's Benchbook for Civil Charges, 66.<sup>1</sup>

To determine what "an ordinarily careful doctor" would do in a particular setting, the jury must look to generally accepted medical practices and procedures. "When a doctor treats a patient, the law does not require perfection. The law does require that the doctors use that degree of knowledge, care, and skill ordinarily possessed and used by doctors in good standing in the doctor's field of medicine, under the same or similar circumstances and that the doctor follow the generally accepted practices and procedures in the profession." "Medical Malpractice: Standard of Care," Judge's Benchbook for Civil Charges, 65.<sup>1</sup>

These practices and procedures are known as clinical and medical practice guidelines and are "statements describing specific diagnostic or therapeutic maneuvers that should or should not be performed in certain specific clinical circumstances." M.R. Chassin, Standards of Care in Medicine, Inquiry, 25 (1988): 438. In the medical malpractice lawsuits, the parties and their medical experts will sometimes disagree on which guideline is the "generally accepted" practice or procedure in the particular clinical circumstances. Thus, one way to address the concerns that LHCPs have about potential liability is to obtain a statewide consensus on the use of pandemic influenza clinical and medical guidelines from the LHCP professional groups and

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<sup>1</sup> See <http://www.charlestonbar.org/CM/ArchivedNewsletters/CivilCharges.doc>, last accessed June 25, 2009.



licensing boards. These groups include, but are not limited to, the Board of Medical Examiners, the Board of Nursing, South Carolina Medical Association, the South Carolina Nursing Association, the South Carolina Hospital Association, and the South Carolina Society for Respiratory Care.

These organizations have the authority to publish advisory opinions and position statements relating to medical practice procedures or policies. See for example S.C. Code of Laws, Section 40-47-10(I)(1) (authority granted to the Board of Medical Examiners to publish advisory opinions relating to practice procedures or policies). In order to encourage consistent, statewide implementation of any clinical and medical guidelines meant to address health care during a PIPHE, these groups and boards should provide clear language indicating support for the pandemic influenza guidelines via position statements and the development of specific codes of ethics dealing with PIPHE.

The practical effect of a consensus on the guidelines is they become the “de facto” generally accepted practices and procedures during a PIPHE in South Carolina. In a subsequent medical malpractice law suit, the question would not be whether the LHCP followed the appropriate guidelines, but whether the LHCP followed the guidelines appropriately. In such a context, a LHCP’s potential tort liability is no more or no less than what it is presently and the question of whether a PHCP is negligent remains a “question of fact” to be determined by the fact finder.

- Recommendations
  - The Clinical Practice Work Group of the South Carolina Pandemic Influenza Ethics Task Force should develop clinical practice guidelines and assessment tools for the triage and treatment of patients with pandemic influenza.
  - The Clinical Practice Work Group of the South Carolina Pandemic Influenza Ethics Task Force should develop clinical practice guidelines and assessment tools that address the allocation of scarce resources, including criteria for the withholding or withdrawing of ventilator support in health care facilities that are experiencing a surge in demand for services due to the influx of patients with pandemic influenza.
  - The South Carolina Pandemic Influenza Ethics Task Force should endeavor to obtain a consensus on the use of the Clinical Practice Work Group’s clinical practice guidelines and assessment tools amongst the LHCP professional groups and licensing boards through the publication of formal policies or letters of support.

Although consensus amongst the LHCP professional groups and licensing boards on the clinical practice guidelines will provide some clarity to medical malpractice lawsuits after the pandemic ends, LHCPs have raised concerns about whether a pre-pandemic consensus on the guidelines will hold true during the pandemic. This concern arises from two important issues: (1) the

extent to which pan flu guidelines differ from day-to-day medical guidelines, and (2) the extent to which LHCPs adhere to the guidelines on a consistent, statewide basis.

It is generally recognized that pan flu guidelines will address the scarcity of medical resources that LHCPs will have to treat cases and will provide guidance on making allocation and rationing decisions, especially on when to withhold or withdraw ventilator support. See for example Devereaux, Asha V., et al., Definitive Care for the Critically Ill During a Disaster: A Framework for Allocation of Scarce Resources in Mass Critical Care, Chest 2008;133;51-66. In this sense, the pan flu guidelines will differ greatly from day-to-day guidelines that are written without the context of a scarcity of resources. LHCPs are concerned that some practitioners will implement the pan flu guidelines and withhold or withdraw ventilator support, while others will defer to the day-to-day guidelines and will not withhold or withdraw ventilator support out of fear of liability.

This inconsistent implementation would have the effect of creating two competing sets of guidelines being used during the pandemic. As a result, LHCPs would be judged afterward not on the quality of the actual health care decisions made, but on the decisions to follow a particular set of clinical guidelines.

Therefore, it is imperative that clear trigger for the implementation of the guidelines be developed. The Legal Work Group recommends that DHEC explore the use of public health laws and authorities under the Emergency Health Powers Act, Sections 44-4-100 to -570, to trigger a statewide implementation of the clinical practice guidelines for the triage and treatment of pan flu patients. The Legal Work Group also recommends that DHEC work with the LHCPs' licensing boards to develop such a trigger.

The Legal Work Group recognizes that the Pandemic Influenza Ethics Task Force is an advisory body and that this recommendation does not constitute legal advice to DHEC. However, the Work Group also recognizes the concerns of LHCPs in the consistent implementation of consensus guidelines as genuine and well founded and encourages DHEC to explore the possibility of a statewide trigger of pan flu triage and treatment guidelines.

#### **H. Notes on Public Response to Date**

In April of 2009, the South Carolina Pandemic Ethics Task Force held public forums in Myrtle Beach, Greenville, Charleston and Columbia to present the Task Force's initial recommendations for the decisions that may be made in a pandemic.

The Myrtle Beach and Greenville public forums were held prior to the occurrence of the H1N1 novel virus in South Carolina. These public forums were attended by a few members of the general and health care public. At these forums, attendees primarily questioned the distribution of antivirals and ventilators, how many were available and who would receive the public stockpiles of antivirals. There were no specific concerns related to the

recommendations, but the forums did provide an opportunity to discuss some of the issues that might arise in a pandemic.

Immediately prior to the Charleston and Columbia public forums, the first cases of H1N1 novel virus were identified in South Carolina. These public forums were well attended; many of the questions and discussions were focused on the H1N1 virus and influenza prevention. However, questions were again raised on the distribution of antivirals, especially to special populations; with no disagreement noted on the Task Force's recommendations. Questions were raised about SCDHEC's plans to reach non-English speaking communities in a pandemic. There was general agreement that health care providers would have to make difficult decisions and the recommendations as listed in the public summary regarding this decision-making were supported by the attendees.

## **VI. Appendices:**

1. Glossary
2. List of South Carolina Pandemic Influenza Ethics Task Force Members
3. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Pandemic Influenza Severity Index
4. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Table 1. Vaccination target groups, estimated populations, and tiers for severe, moderate, and less severe pandemics as defined by the Pandemic Severity Index (PSI)
5. U.S. Department of Health and Human Services, "Guidance on Antiviral Drug Use during an Influenza Pandemic", Table: Settings and strategies for antiviral drug use during an influenza pandemic
6. Clinical Practices: Adult Self-Assessment Tool
7. Approaches to Optimizing Hospital Capacity
8. Specific Clinical Practice Guidelines
9. SOFA Scoring
10. Multi-principle Strategy for ventilator allocation
11. Bibliography

## **APPENDIX 1. GLOSSARY**

Acute Care

Alternate care sites

Co-morbid conditions

Countermeasures

Critical Care

Emergency Health Powers Act

Epidemic

Intensivist

Isolation

Mitigate

Palliative Care, palliation

Pandemic

Pandemic severity

Pathogenic

Personal Protective Equipment

Prophylaxis

Quarantine

Self-Determination

Social Distancing

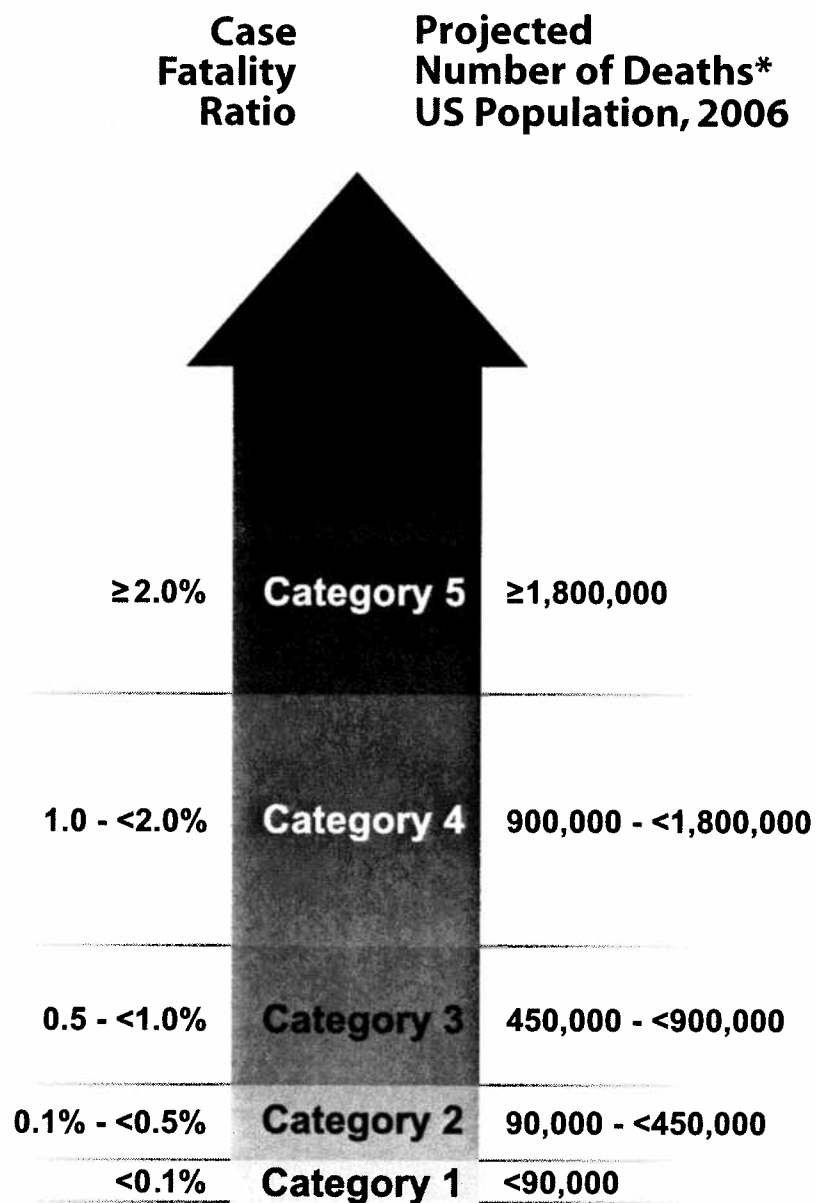
SOFA Score

Surge capacity

Triage

**APPENDIX 2. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, CENTERS  
FOR DISEASE CONTROL AND PREVENTION (CDC), PANDEMIC SEVERITY LEVELS**

Figure 4. Pandemic Severity Index



\*Assumes 30% Illness Rate and Unmitigated  
Pandemic Without Interventions

### **APPENDIX 3. SOUTH CAROLINA PANDEMIC INFLUENZA TASK FORCE MEMBERS**

Appleton, Lynne Bailey Bailey Appleton, LLC	Bullington, Eric Medical Reserve Corps	Gabel, Harold, MD SCDHEC
Apt, Carol, Ph.D. SC State University	Bundrick, LeeAnn SC Board of Pharmacy	Gibson, Jerry, MD SCDHEC
Austin, Ann, RN SCDHEC	Carnsew, Lori, MD Academy of Family Physicians	Gimarc, Jerry Dell
Bainer, Joan, RN SC Board of Nursing	Carter, W. Stewart SCDHEC	Gore, Betty, RN SCDHEC
Ball, Robert, MD SCDHEC	Clancy, Dawn, MD American College of Physicians, SC Chapter	Gulledge, Deloris, Ph.D. SC Coroner's Association C.A.R.E. Team
Barteet, Raymond SCDHEC	Clay, George, Ph.D. Clemson University	Hammond, Lynn SC Department of Education
Beasley, Jim SCDHEC	Culbreath, Donna SCDHEC	Harder, Diana SCDHEC
Beasley, Phyllis SCDHEC	Dukes, Pam SCDHEC	Hendricks, CPL Joseph SC Highway Patrol
Bell, Ann SCDHEC	Duffie, Tanis SCDHEC	Hollingsworth, Shirley SCDHEC
Bell, Linda, MD SCDHEC	Eagerton, David SC Law Enforcement Division	Hovis, Roger SCDHEC
Brought, Eloise Y. USDA APHIS	Epley, Joanne SCDHEC	Kinney, Ron SCDHEC
Bryan, Charles Providence Hospitals	Epright, Carmela, Ph.D. Furman University	Kitchens, Greg SCDHEC
Bullard, P.D. Chair, SCMA BioEthics Committee	Fabian, George T., MD SCDHEC	Kneece, Rev. Brenda SC Christian Action Council
	Foster, Richard, MD SC Hospital Association	Kretschmar, Kendall SC Emergency Management Division



Lane, Scott SC Respiratory Care Association	Meaux, Corey SCDHEC	Reece, Venaye US Dept. of Agriculture-APHIS
Langston, Randy SCDHEC	Meredith, Jennifer, Ph.D. SCDHEC	Richter, Jane, Ph.D. Univ. of SC – Center for Public Health Preparedness
Larson, Eric, MD Medical University of SC	Mitchell, Justin, MD Univ. of SC School of Medicine	Richter, Paul SC Hospital Association
Laymon, Major Paul SC National Guard	Myer, Michelle, RN SCDHEC	Sade, Robert, MD Medical Univ. of SC
Learner, R. Max, Ph.D. SCDHEC	Nesmith, Al Medical Univ. of SC	Satterwhite, Cliff SC Baptist Convention
Lee, Randy SC Nursing Home Association	Niemeyer, Mary Helen, MD SCDHEC	Schmidt, Michael, MD Medical Univ. of SC
Lenard, Delorias US Dept. of Agriculture-SC Area Office	Owens, William, MD Palmetto Richland Hospital	Schneider, Phil, Ph.D. Coastal Carolina University
Limehouse, Chaplain Capers Roper St. Francis Hospital	Parks, Robert SC Funeral Directors Association	Scott, Lance, MD Medical Univ. of SC
Limehouse, Walter, MD Chair, Medical University of South Carolina Ethics Committee	Patterson, Libba Univ. of SC School of Law	Shelton, Steve, MD SC College of Emergency Physicians
Martin, Brenda, RN President, SC Board of Nursing	Patterson, Mike Salvation Army	Smith, Alonzo SCDHEC
McElveen, Lee S. SC Commission for Minority Affairs	Penn, Matthew SCDHEC	Sprague, Stuart, MD Anderson Medical Health Center
McKeown, Robert University of South Carolina	Peralta, Sgt. G. B. Dept. of Public Safety	Stanley, Covia, MD SCDHEC
	Rawls, Cathy SC Coroner's Association	Stillwell, Steve Salvation Army

Sweigart, Cindy  
SCDHEC

Thomas, Johnny L.  
SC Emergency Management  
Division

Tolomea, Brenda  
SCDHEC

Waddell, Lisa, MD  
SCDHEC

Watts, Gary  
SC Coroner's Association

Wells, William  
SC Dept. of Mental Health

Williams, Steve  
Haynsworth, Sinkler, Boyd, PA

Wozniak, Arthur  
SCDHEC

Young, Vicki  
SC Primary Health Care  
Association

**APPENDIX 4. TABLE 1. VACCINE TARGET GROUPS, ESTIMATED POPULATIONS, AND TIERS FOR SEVERE, MODERATE AND LESS SEVERE PANDEMICS AS DEFINED BY THE PANDEMIC SEVERITY INDEX (PSI)**

**Table 1.** Vaccination target groups, estimated populations, and tiers for severe, moderate and less severe pandemics as defined by the Pandemic Severity Index (PSI). Persons in occupational groups not specifically targeted for vaccination in Moderate and Less Severe pandemics are targeted according to their age and health status in the general population.

		Tier 1	Tier 2	Tier 3	Tier 4	Tier 5	Not Targeted**	Severity of Pandemic		
Category	Target Group	Estimated Number*					Severe	Moderate	Less severe	
Homeland and national security	Deployed and mission critical personnel	700,000								
	Essential support & sustainment personnel	650,000								
	Intelligence services	150,000								
	Border protection personnel	100,000								
	National Guard personnel	500,000								
	Other domestic national security personnel	50,000								
	Other active duty & essential support	1,500,000								
Health care and community support services	Public health personnel	300,000								
	Inpatient health care providers	3,200,000								
	Outpatient and home health providers	2,500,000								
	Health care providers in LTCFs	1,600,000								
	Community support & emergency management	600,000								
	Pharmacists	150,000								
	Mortuary services personnel	50,000								
Critical infrastructure	Other important health care personnel	300,000								
	Emergency services sector personnel (EMS, law enforcement and fire services)	2,000,000								
	Mfrs of pandemic vaccine & antivirals	50,000								
	Communications/IT, Electricity, Nuclear, Oil & Gas, and Water sector personnel	2,150,000								
	Financial clearing & settlement personnel									
	Critical operational & regulatory government personnel									
	Banking & Finance, Chemical, Food & Agriculture, Pharmaceutical, Postal & Shipping, and Transportation sector personnel	3,400,000								
General population	Other critical government personnel									
	Pregnant women	3,100,000								
	Infants & toddlers 6-35 mo old	10,300,000								
	Household contacts of infants < 6 mo	4,300,000								
	Children 3-18 yrs with high risk condition	6,500,000								
	Children 3-18 yrs without high risk	58,500,000								
	Persons 19-64 with high risk condition	36,000,000								
Persons >65 yrs old	38,000,000									
	Healthy adults 19-64 yrs old	123,350,000								

\*Estimates rounded to closest 50,000. Occupational target group population sizes may change as plans are developed further for implementation of the pandemic vaccination program

\*\*Persons not targeted for vaccination in an occupational group would be vaccinated as part of the General Population based on their age and health status.

**APPENDIX 5. TABLE. SETTINGS AND STRATEGIES FOR ANTIVIRAL DRUG USE DURING AN INFLUENZA PANDEMIC AND RATIONALES.**

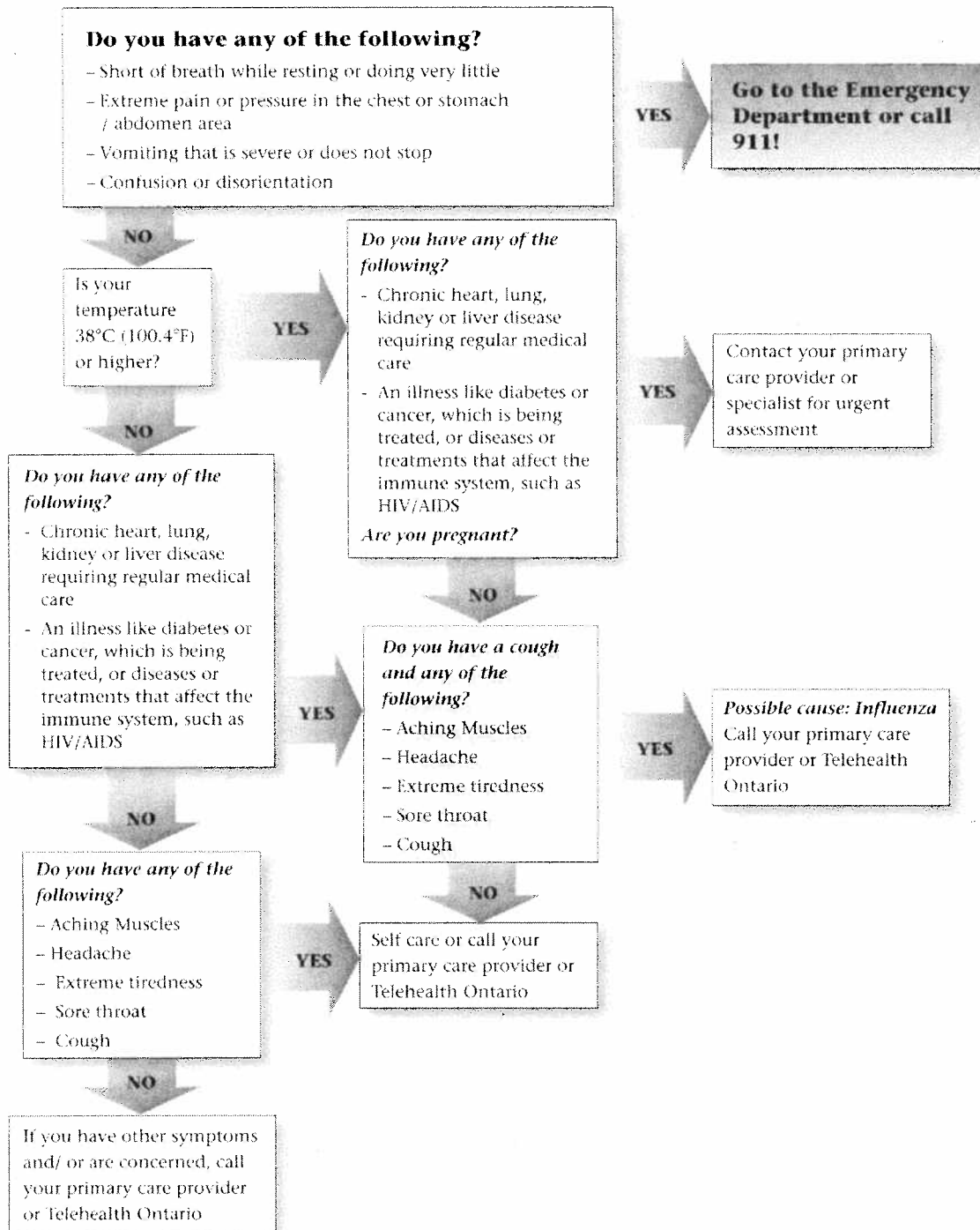
**Table. Settings and strategies for antiviral drug use during an influenza pandemic and rationales. 2**

Setting and target population	Antiviral strategy	Rationale	Pandemic response goals addressed by antiviral strategy	Estimated number of regimens (million)
<b>Recommendations for antiviral drugs from public sector stockpiles</b>				
Initial pandemic outbreaks overseas and in the U.S.	Treatment; PEP, targeted prophylaxis	-- Effective containment of the initial outbreak of a novel influenza virus strain may prevent the pandemic -- Quenching efforts overseas and in the U.S will slow pandemic spread and provide more time for preparedness	Slow pandemic spread	6
Exposed travelers entering the U.S. early in a pandemic	PEP	-- Contributes to a risk-based policy to reduce the entry of infected persons and delay U.S. outbreaks	Slow pandemic spread	
Persons with pandemic influenza illness	Treatment	-- Reduces influenza complications, hospitalization, and death -- Reduces duration of illness and transmission of infection -- Meets patient and provider expectations for medical care	Reduce health impacts	79*
Outbreak control in closed settings (e.g., nursing homes, prisons)	PEP	-- High risk of illness and death when outbreaks occur in closed settings -- Documented success of PEP for seasonal outbreaks -- Consistent with accepted public health practice -- Protects those in whom vaccination may be less effective	Reduce health impacts	5
<b>Recommendations for antiviral drugs primarily from private sector stockpiles</b>				
Healthcare and emergency service workers	Outbreak (preexposure) prophylaxis for workers with high-risk exposure	-- Reduces infection and absenteeism in a critical workforce -- Protects those at highest occupational risk -- Reduces chance of transmitting infection to high-risk patients with illnesses other than influenza	Reduce health impacts Minimize societal disruption	103
PEP given exposure of other workers				
Persons who are severely immuno-compromised	PEP	-- High risk for severe complications and mortality from pandemic influenza, if infected -- Antiviral drugs are the only option for disease prevention	Reduce health impacts	2
<b>TOTAL NUMBER OF ANTIVIRAL DRUG REGIMENS FOR FULL IMPLEMENTATION</b>				<b>195</b>

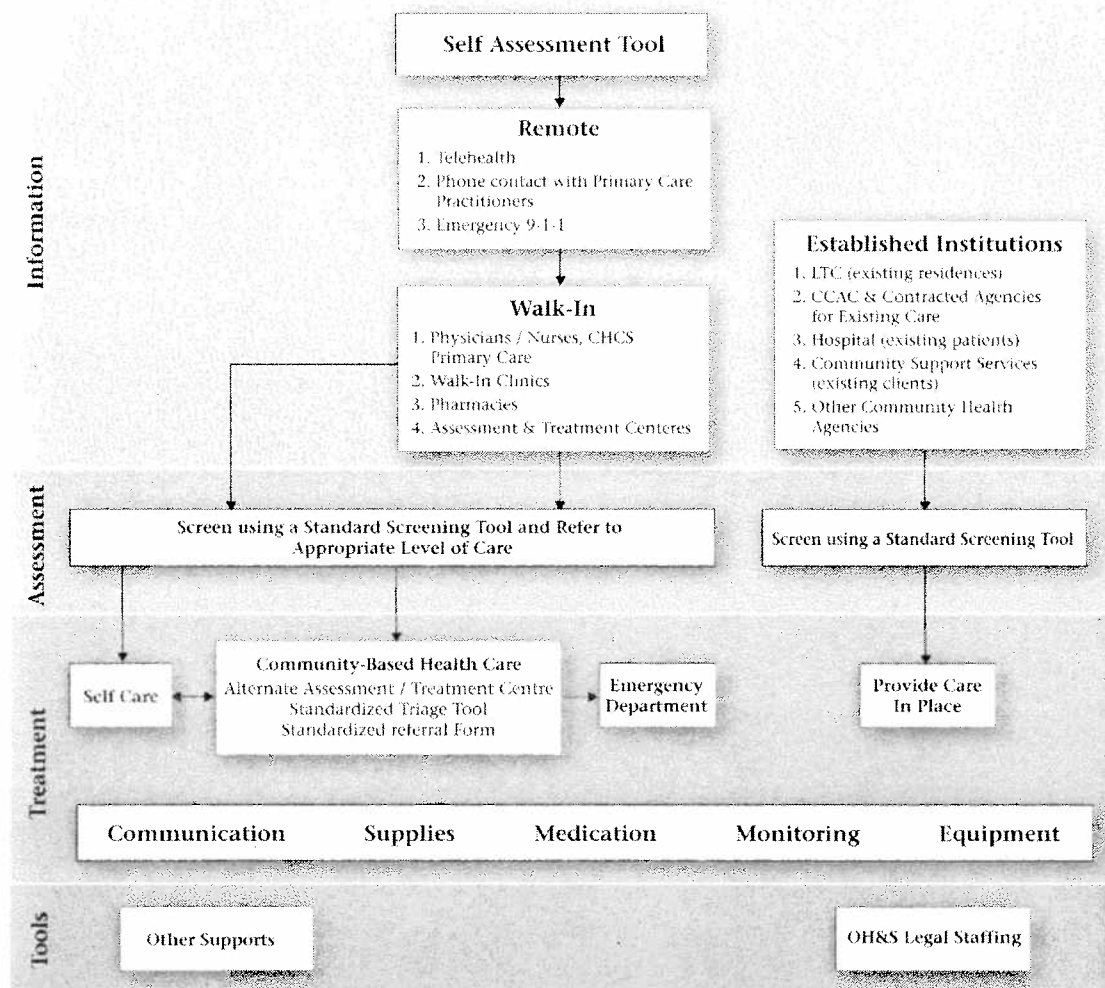
**\*A prior estimate of 75 million regimens has served as the basis for public sector stockpiling. The 79 million regimen estimate was calculated 4 using updated planning assumptions**

## APPENDIX 6. CLINICAL PRACTICES: ADULT SELF-ASSESSMENT TOOL

### Adult Self-Assessment Tool



## Continuing Influenza-Like Illness Assessment



Communication: Public Health Hotline; Media (Radio & TV, etc.); Public Education



## APPENDIX 7. APPROACHES TO OPTIMIZING HOSPITAL CAPACITY

Capacity	Activity
Physical Capacity	<ul style="list-style-type: none"> <li>• Defer any services for non-life-threatening conditions where no severe adverse health consequences are anticipated for the delay</li> <li>• Discharge Alternate Level of Care (ALC) patients to Long-Term Care homes when beds are immediately available</li> <li>• Discharge acute inpatients to home care when care can be provided safely in that environment</li> <li>• Discharge acute patients to family and self care when care can be provided safely in the environment</li> <li>• Create “flex beds” from reserved beds or recently closed beds</li> <li>• Use ventilator capacity anywhere in the hospital where sufficient oxygen capacity exists (e.g. ER, post-anesthetic care units), cohort infectious patient and noninfectious patients</li> <li>• Deploy freed-up beds for influenza patients</li> </ul>
Hospital Staffing	<ul style="list-style-type: none"> <li>• Re-deploy clinical staff from deferred services</li> <li>• Defer staff holidays and leaves of absence until pandemic ends</li> <li>• For staff willing to work extra hours, establish 12-hour shifts up to the maximum recommended number of days per staff</li> <li>• Training non-clinical staff to provide support services such as meals,</li> </ul>

	<p>personal care, and patient movement for treatment, site cleaning and support for health care workers and their families, so the workers can do their job (e.g. child care, pet care)</p> <ul style="list-style-type: none"> <li>• Recruit clinical agency staff in coordination with other hospitals in the immediate geographic area</li> <li>• Encourage members of the public to take home health care courses before the pandemic so they know how to prevent infection and provide supportive care for family members who are ill; train family members of hospital patients to provide home health care</li> <li>• Cross-train clinical staff for influenza care and other essential services during a pandemic and other large-scale emergencies</li> </ul>
Clinical Practices	<ul style="list-style-type: none"> <li>• Adopt clinical care practices to optimize hospital capacity</li> </ul>

## APPENDIX 8. SPECIFIC CLINICAL PRACTICE GUIDELINES

### Adult Palliative Care Orders

Page 1 of 3

Patient Name

MRN

PATIENT ID LABEL

#### Instructions:

Check Yes (Y) block for all applicable orders and fill in any blanks and other boxes for those orders.

Check No (N) block for all orders not applicable.

Orders are not valid unless either Yes or No block checked.

ALLERGIES/DRUG SENSITIVITY: 1. 2. 3. 4.

Another brand of a generically equivalent product identical in dosage form and content of active ingredient may be administered unless checked.

Y N 1. Medical Service:

Attending: Pager ID

Resident: Pager ID

Y N 2. DIAGNOSIS: Palliative care (v66.7)

Y N 3. TREATMENT GOALS: Comfort care until discharged with hospice

Y N 4. CODE STATUS: Full Code Allow Natural Death (AND Orders required)

Y N 5. VITALS: Daily Comfort assessment and RR Q4 hours and PRN Routine

Y N 6. PARAMETERS TO NOTIFY PHYSICIAN:

Patient remains uncomfortable after intervention of adult palliative care orders

No vital sign parameters to notify physician

(NOTE: If signs of fever present, take temperature and treat per orders)

Other

Y N 7. NURSING: Assess every for signs of inadequate control of symptoms

(pain, dyspnea, agitation, fever)

Oral care every 4 hours. Teach family if they desire.

Oral suction PRN (NO DEEP SUCTION)

Oxygen nasal prongs at 2 liters per minute PRN dyspnea (titrate to comfort)

Bedside Commode PRN

Condom Catheter PRN urinary incontinence

Straight Catheter PRN bladder distension

Foley Catheter to drainage PRN urinary retention/urinary incontinence

Implement Fall Prevention Precautions

Skin integrity care

Y N 8. ACTIVITY: Out of bed ad lib Out of bed to chair

Bed rest Other

Y N 9. DIET: NPO Oral diet type

Parenteral Nutrition (must complete adult order form)

Enteral Nutrition (must complete adult order form)

Y N 10. IV: Saline lock

If IV lost, do not replace

Y N 11. CONSULTATIONS:

Physical Therapy for family instruction on "Activities of Daily Living" and assessment of equipment needs

Wound Care - Reason:

Chaplain - Reason:

Pediatric Palliative Care - Reason:

Physician Signature Pager ID Date Time AM/PM

pallorders OTE 900134 Rev. 5/07

## Adult Palliative Care Orders

Page 2 of 3

Patient Name

MRN

PATIENT ID LABEL

ALLERGIES/DRUG SENSITIVITY: 1. 2. 3. 4.

Y N 12. MEDICATIONS (Review Drug Sensitivities):

Another brand of a generically equivalent product identical in dosage form and content of active ingredient  
may be administered unless checked < .>

### Medication Dose Route Frequency Comments

#### A. PAIN AND / OR DYSPNEA

Acetaminophen	650 mg	PO	PR	PEG	PRN	Q4H	Mild pain or temp > 101° F
Ibuprofen	mg	PO		PEG	PRN	Q6H	Mild / moderate pain or if fever unresponsive to acetaminophen
Morphine Sulfate CR	mg	PO	PR			Q12H	
Doses available: 15, 30, 60, 100, and 200 mg tablets							
Morphine Sulfate IR	mg	PO	SL	PEG	PRN	Q1H	Pain,
common doses available 10, 15 mg tablets or elixir (Roxanol) 10 mg per 5 mL, 20 mg per 5 mL, or 20 mg per 1 mL							
Fentanyl Patch	micrograms per hour		TD (transdermal)			Q3 days	Pain (opioid tolerant ONLY)
Doses available (microgram/hour): 25, 50, 75, 100							
Fentanyl lozenges	micrograms TM (transmucosal)				PRN	Q1H	Pain (opioid tolerant ONLY)
Doses available: 200, 400, 600, 800, 1200, 1600 microgram lozenges.							
Usually start with 200 or 400 microgram							
Morphine Sulfate	mg	SC	IV		PRN	Q H	Pain or dyspnea
Hydromorphone	mg	SC	IV		PRN	Q H	Pain or dyspnea
Gabapentin	mg	PO				Q H	Neuropathic pain
Oxycodone	mg	PO	PEG		PRN	Q H	Pain or dyspnea.
Doses available: 5 mg tablets or as elixir 1 mg/mL							

AND End-of-Life opiate infusion orders continuous IV / SC:

[complete Adult Continuous Analgesia and Dyspnea Opioid Therapy Orders for End-of-Life patients]

## B. DELIRIUM

Haloperidol	mg	PO	IV	PEG	SC	PRN	Q H	Restlessness due to terminal delirium
Risperidone	mg	PO		PEG	ODT	PRN	Q H	Restlessness due to terminal delirium

## C. NAUSEA AND VOMITING

Metoclopramide	mg	PO	PEG	IV		PRN	AC & HS	Nausea and / or vomiting
Prochlorperazine	mg	PO	PEG	IV	PR	PRN	Q8H	Nausea and vomiting (first line if nausea and vomiting due to opioids)
								(PR dose 25 mg, other routes, 10 mg)
Haloperidol	mg	PO	PEG	IV	SC	PRN	Q H	Nausea and / or vomiting

Physician Signature

Pager ID

Date

Time

AM/PM

## Adult Palliative Care Orders

Page 3 of 3

Patient Name

MRN

PATIENT ID LABEL

ALLERGIES/DRUG SENSITIVITY: 1. 2. 3. 4.

Another brand of a generically equivalent product identical in dosage form and content of active ingredient

may be administered unless checked.>

YN 12. MEDICATIONS (Review Drug Sensitivities):

Medication	Dose	Route	Frequency	Comments
------------	------	-------	-----------	----------

### D. BOWEL REGIMEN

Docusate Sodium	100 mg	PO PEG	PRN BID	Constipation: First line: give regularly initially.  Hold for excessive bowel movements
Senna (Senokot ®)	mg (Available in 8.6 mg tab or 8.8 mg/5 mL syrup)	PO PEG	PRN Q day	Constipation: First line: give regularly initially Hold for excessive bowel movements.
Bisacodyl (Dulcolax ®) Suppository	10 mg	PR	PRN Q12H	If no bowel movement in past 36 hours
Lactulose	mL	PO PEG	PRN Q H	If no bowel movement in 48 hours
Loperamide	2 mg	PO PEG	PRN Q H	Diarrhea

### E. OTHER SYMPTOMS

Lorazepam	mg	PO IV SL	PRN Q1H	Anxiety
Midazolam	mg	IV SC	PRN Q H	Seizure and CALL Physician
Chlorpromazine	25 mg	PO IV	PRN Q6H	Hiccups
Scopolamine	1 patch 2 patches	TD (transdermal)	Q 3 days	Excessive secretions
Dose: 1.5 mg per patch. SC, Q4H, twice, until TD mechanism effective.				
Atropine 1% ophthalmic	2 drops	SL (sublingual)	PRN Q4H	Excessive secretions

solution

Glycopyrrolate	0.1 mg 0.2 mg	IV	SC	PRN	Q4H	Excessive secretions
Baclofen	mg		PO		QID	Spasms
Diphenhydramine	25 mg	PO	IV	PRN	Q6H	Itching
Dexamethasone	mg		IV		Q H	
Prednisone	mg	PO			Q H	

## F. OTHER MEDICATIONS

(dose / route / frequency / indication)

(dose / route / frequency / indication)

(dose / route / frequency / indication)

(dose / route / frequency / indication)

Physician Signature	Pager ID	Date	Time	AM/PM
---------------------	----------	------	------	-------

Adult Continuous Analgesia & Dyspnea

Patient name

Opioid Therapy Orders

MRN

For use in End-of-Life Patients Only

Patient ID Label

Allergies/Drug Sensitivity: 1

2

3

4

For use only with Adult Palliative Care Orders

Before starting continuous opiates at End-Of-Life for pain & dyspnea



document the following in the medical record:

☐ goals of treatment to include continuous opioid therapy for pain and/ dyspnea for end of-life care

☐ AND order complete & in medical record

1. Opiate Delivery Route: ☐ SC ☐

If SC: no maintenance IV

IV: if no maintenance fluids,

infuse IV PCA maintenance fluids Dextrose 5% ☐ normal saline ☐ @      ml/h

2. Medication: ☐ Morphine 1 mg/ml ☐ Morphine 5 mg/ml ☐ Hydromorphone 1 mg/ml  
☐ Other

3. Loading Dose: ☐ no

☐ yes      mg IV q 10 min until patient reports or exhibits relief of pain / dyspnea

Maximum total loading dose      mg

4. Pump settings: Incremental dose      mg  
Lock-out interval (delay)      minutes  
1 hour limit      mg/hr

5. Pump settings: Initial basal rate      mg IV h hour

6. If pain / dyspnea not controlled, patient may receive bolus of  
☐ Morphine      mg Q10 min x 3 ☐ PRN for pain/dyspnea ☐ Q hour ☐ Q 2 hr  
☐ Hydromorphone      mg Q10 min ☐ PRN for pain/dyspnea ☐ Q hour ☐ Q 2 hr  
☐ Other

7. Side effects: See palliative care order set

8. Monitoring: per 24 hr pain management flowsheet

NOTE: Expect falling respiratory rate in naturally dying process. If respiratory rate < 12 & no signs of dyspnea present, patient has no need for increased opiate drip or rescue doses. Agonal respirations are a normal part of dying

Physician name

Physician Signature

pager

date

time

am/pm

[PEDIATRIC PALLIATIVE CARE MODEL]

## APPENDIX 9. SOFA SCORING TOOL

SOFA scoring comprises criteria for inclusion and exclusion from critical care and minimum qualifications for survival. Scores place patients into three categories: blue patients receive palliation; red patients have highest priority for ventilation, followed by yellow patients; green patients receive acute care outside of the critical care units. SOFA reassessments define movement between categories.

SOFA identifies patients for admission to critical care, primarily due to respiratory failure. The ability to provide invasive ventilatory support differentiates critical care units from other acute care areas, such as step-down units. However, expanded care units for surge capacity may offer hemodynamic support and other advanced care in areas which have appropriate monitoring but do not typically provide that level of care. If hemodynamic support is not available elsewhere, non-ventilator patients may receive critical care.

SOFA excludes from critical care:

- 1) People with very poor prognosis/chance of survival even when treated with aggressive critical care
  - a. severe burns or inhalation injury
  - b. unwitnessed or recurrent cardiac arrest patients or no response to prompt electrical interventions
  - c. patients with a SOFA score > 11 whose mortality rate exceeds 90% even with full critical care during normal circumstances;
- 2) People needing level of resources that cannot be met during pandemic
  - trauma or medical conditions requiring high volume blood transfusions , due to high mortality and limited supply of uninfected blood products;
- 3) People with advanced medical illnesses with high short-term mortality even without concurrent critical illness.
  - a. advanced cancer or immunosuppression
  - b. end-stage organ failure

Cardiac: NYHA stage III –IV heart failure

Pulmonary: FEV1 < 25% predicted

Hepatic: MELD score > 20

Renal: dialysis dependent

*Neuro: severe, irreversible neurological event/condition with high expected mortality; This criterion accepts that no organ transplants will occur during pandemic.*

Minimum Qualifications for Survival (MQS) represents the ceiling on resources allocated to one individual. SOFA requires ongoing, 48 hour & 120 hours patient reassessments. Greater pandemic severity will require more frequent SOFA scoring. If the patient ever develops a SOFA score of  $\geq 11$  or any other exclusion criteria, she moves to palliative care. MQS attempts to identify early those patients not improving or likely to have poor outcome, since scarce resources preclude prolonged critical care during a pandemic.

## SOFA Score

*JAMA. 2001;286:1754-1758*

- **Sofa score (0-24)**
- **tracks organ failure in six system**
- **validated predictor of mortality in ICU settings**
- **Predictive values**
  - Mean > highest >  $\Delta$  –SOFA > initial score (less than 11)

# SOFA Score

JAMA. 2001;286:1754-1758

**Table 1.** The Sequential Organ Failure Assessment (SOFA) Score\*

Variables	SOFA Score				
	0	1	2	3	4
Respiratory Pao <sub>2</sub> /Fio <sub>2</sub> , mm Hg	>400	<400	<300	<200†	<100†
Coagulation Platelets, ×10 <sup>3</sup> /μL‡	>150	<150	<100	<50	<20
Liver Bilirubin, mg/dL‡	<1.2	1.2-1.9	2.0-5.9	6.0-11.9	>12.0
Cardiovascular Hypotension	No hypotension	Mean arterial pressure <70 mm Hg	Dop <5 or dob (any dose)§	Dop >5, epi <0.1, or norepi <0.15	Dop >15, epi >0.1, or norepi >0.15
Central nervous system Glasgow Coma Score Scale	15	13-14	10-12	6-9	<6
Renal Creatinine, mg/dL or urine output, mL/dL	<1.2	1.2-1.9	2.0-3.4	3.5-4.9 or <500	>5.0 or <200

\*Norepi indicates norepinephrine; Dob, dobutamine; Dop, dopamine; Epi, epinephrine; and Fio<sub>2</sub>, fraction of inspired oxygen.  
†Values are with respiratory support.  
‡To convert bilirubin from mg/dL to μmol/L, multiply by 17.1.  
§Adrenergic agents administered for at least 1 hour (doses given are in μg/kg per minute).  
¶To convert creatinine from mg/dL to μmol/L, multiply by 88.4.

## Critical Care Triage Tool

Critical Care Triage Tool (Initial Assessment)		
Color Code	Criteria	Priority/Action
Blue	<ul style="list-style-type: none"> <li>Exclusion Criteria*</li> <li>or</li> <li>SOFA &gt;11*</li> </ul>	Medical Mgmt +/- Palliate & d/c
Red	<ul style="list-style-type: none"> <li>SOFA ≤7</li> <li>or</li> <li>Single Organ Failure</li> </ul>	Highest
Yellow	<ul style="list-style-type: none"> <li>SOFA 8-11</li> </ul>	Intermediate
Green	<ul style="list-style-type: none"> <li>No significant organ failure</li> </ul>	Refer or d/c, reassess as needed

## Critical Care Triage Tool

Critical Care Triage Tool (48-Hour Assessment)		
Color Code	Criteria	Priority/Action
Blue	<ul style="list-style-type: none"> <li>Exclusion Criteria</li> <li>or</li> <li>SOFA &gt;11</li> <li>or</li> <li>SOFA 8-11 no Δ</li> </ul>	Palliate & d/c from CC
Red	<ul style="list-style-type: none"> <li>SOFA &lt;11 and decreasing</li> </ul>	Highest
Yellow	<ul style="list-style-type: none"> <li>SOFA &lt;8 no Δ</li> </ul>	Intermediate
Green	<ul style="list-style-type: none"> <li>No longer ventilator dependent</li> </ul>	d/c from CC

## Critical Care Triage Tool

Critical Care Triage Tool (120-Hour Assessment)		
Color Code	Criteria	Priority/Action
Blue	<ul style="list-style-type: none"> <li>Exclusion Criteria*</li> <li>or</li> <li>SOFA &gt;11*</li> <li>SOFA &lt;8 no Δ</li> </ul>	Palliate & d/c from CC
Red	<ul style="list-style-type: none"> <li>SOFA score &lt;11 and decreasing progressively</li> </ul>	Highest
Yellow	<ul style="list-style-type: none"> <li>SOFA &lt;8 minimal decrease (&lt;3-point decrease in past 72h)</li> </ul>	Intermediate
Green	<ul style="list-style-type: none"> <li>No longer ventilator dependent</li> </ul>	d/c from CC

[INSERT CHART FOR COMPUTING / TRACKING SOFA and /or MULTIPRINCIPLE SCORES]

## APPENDIX 10. MULTI-PRINCIPLE STRATEGY FOR VENTILATOR ALLOCATION

### Annals of Internal Medicine

**Table 3.** Illustration of a Multiprinciple Strategy to Allocate Ventilators During a Public Health Emergency

Principle	Specification	Point System*			
		1	2	3	4
Save the most lives	Prognosis for short-term survival (SOFA score)	SOFA score <6	SOFA score, 6–9	SOFA score, 10–12	SOFA score >12
Save the most life-years	Prognosis for long-term survival (medical assessment of comorbid conditions)	No comorbid conditions that limit long-term survival	Minor comorbid conditions with small impact on long-term survival	Major comorbid conditions with substantial impact on long-term survival	Severe comorbid conditions; death likely within 1 year
Life-cycle principle†	Prioritize those who have had the least chance to live through life's stages (age in years)	Age 12–40 y	Age 41–60 y	Age 61–74 y	Age ≥75 y

SOFA = Sequential Organ Failure Assessment.

\* Persons with the lowest cumulative score would be given the highest priority to receive mechanical ventilation and critical care services.

† Pediatric patients may need to be considered separately, because their small size may require the use of different mechanical ventilators and personnel.

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June 23, 2009

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